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Cycling induced by Functional Electrical Stimulation: a case study inspired by the experience of CYBATHLON 2020

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Contents

Abstract

INTRODUCTION

Functional electrical stimulation in subjects with spinal cord injury

Spinal cord injury (SCI) disrupts the descending motor fibers from the motor cortex to the spinal motoneurons, and the ascending somato-sensory fibers from the spinal cord to the brain. Intrinsic circuits below the level of injury remain intact but disconnected from descending controls of the cerebral cortex [1]. The term Functional Electrical Stimulation (FES) refers to the stimulation of an intact lower motor neuron to activate plegic or paretic muscles in a precise sequence and magnitude so as to directly accomplish or support functional tasks [2]. FES provides a means of mobilising intact lower limbs and has been shown to be very effective in preventing secondary complications like blood pooling in the lower limbs, low blood pressure and deep venous thrombosis, when used regularly over a period of time [3, 4, 5]. Positive adaptations of bone mineral density and increased muscle strength are further benefits following FES-induced training [6, 7]. These improvements help to reduce the risk of pressure sores and fractures [8]. FES has also demonstrated the capacity to improve cardiopulmonary fitness [9], postponing muscle atrophy [10, 11], and reducing spasticity [12, 13]. Positive psycho-social adaptations have also been reported among SCI individuals who undergo FES exercises [4].

Cycling induced by functional electrical stimulation

In the first half of the 1980s, first examples of people with SCI able to produce cyclical leg motion by means of controlled sequential stimulation of the large leg-actuating muscles (typically the quadriceps, hamstrings and the gluteal muscle groups) were shown. While most previous studies utilized stationary ergometers, a number of mobile devices were also proposed [14, 15, 16, 17], raising the possibility that FES-cycling might become a recreational activity [18]. People with SCI experience a reduction in physical activity and an increased difficulty in accomplish everyday life tasks that make them feel highly dependent upon caregivers. These are some of the reasons why they are at greater risk for poor mental health, including depression [19]. Developing an exercise program that is effective and enjoyable is paramount for this population [20]. One of the main limitation of FES-cycling for people with SCI, mainly when performed outdoor, is the low efficiency, i.e. the ratio of external work output to metabolic energy input, which is much lower than that of able-bodied subjects cycling under volitional control. Therefore, maximization of cycling efficiency is one of the most important challenges in mobile cycling [18], since the low peak powers produced by FES (approximately 25 W) are not enough to overcome rough surfaces, slight inclines or headwinds [20]. The other major factor that limits the use and effectiveness of FES in all contexts is the well-known problem of the rapid onset of muscle fatigue [8].

The problem of the rapid onset of muscle fatigue in FES applications

It is observed that the rate of fatigue during FES-induced muscle contractions is much greater than that observed during volitional contractions [21]. One of the several factors that contributes to this phenomenon is the fact that FES recruits motor units in a synchronous manner meaning that all the motor units are activated at the same time, instead of rotating through the motor units as is done by the nervous system during physiological muscle contractions. For this reason, achieving tetanic contractions with FES requires a much higher stimulation frequency (20-40 Hz) that results in a much more rapid onset of muscle fatigue [22, 21]. Furthermore, FES is believed to recruit the large fast-twitch fatiguable motor units before the small slow-twitch fatigue resistant motor units. In addition, paralysed muscle are prone to disuse atrophy and are demonstrated to undergo histochemical changes that result in a shift towards fast-twitch, readily-fatiguable muscle fibers [23].

Stimulation strategies to postpone the onset of muscular fatigue

Several investigations have examined the effects of various stimulation patterns on force output and neuromuscular fatigue. Several studies compared stimulation patterns based on constant frequency trains (CFTs), variable frequency trains (VFTs) and doublet frequency trains (DFTs) [24, 25, 26, 27, 27, 28]. Traditionally, FES uses CTFs, i.e. brief stimulation pulses separated by regular interpulse intervals [29]. VFTs consists of trains characterized by an initial doublets, i.e. two closely spaced pulses, typically 5-10 μs apart) followed by pulses at a constant frequency [30], while in DFTs closely spaced pulse pairs ($\sim$ 5ms interpulse intervals) are separated by longer intervals (inter-doublet intervals) [31]. VFTs and DFTs exploit the nonlinear force summation [32] and the catchlike muscle property [33].

FES is usually delivered to one muscle group through a pair of stimulation electrodes, resulting in a simultaneous activation of all recruited motor units [34]. Since one reason for rapid muscular fatigue is the activation of only a subset of motor units of the corresponding muscle [35, 36], multi-electrode setups have been developed, which allow stimulation patterns to target different motor units within the same muscle group, showing some advantages in reducing muscle fatigue [5, 37, 38, 39, 40, 41]. This stimulation strategy consists in sending stimulation pulses, one after another, to every single electrode sequentially, resulting in a fused response from the low frequency unfused responses of individual electrodes. Such sequentially applied stimulation is referred to as spatially distributed sequential stimulation (SDSS) [40].

The CYBATHLON championship

The CYBATHLON is a unique championship organized by ETH Zurich in which people with physical disabilities compete against each other to complete everyday tasks using state-of-the-art technical assistance systems. On November 13th 2020, the CYBATHLON 2020 Global Edition took place in a remote modality, due to the Covid-19 pandemic. The disciplines of CYBATHLON include a FES-bike race during which pilots with a complete SCI had to cover a distance of 1200 m within 8 minutes using a passive trike integrated with FES [42].

Objectives

This master thesis work had two main goals:

1. To optimize a prototype of FES-bike for paraplegics, to organize and supervise the training sessions of the pilot and to determine the optimal stimulation parameters for the participation in the CYBATHLON 2020 Global Edition (www.cybathlon.ethz.ch).

2. To design a case study based on the experience of the CYBATHLON, with the aim to compare different stimulation strategies (constant frequency, DFTs, SDSS) in terms of FES-induced muscular fatigue. Since no previous studies specifically investigating the effect of different stimulation strategies during FES-cycling could be found, this case study aimed at filling this gap in the literature.

MATERIALS AND METHODS

Experimental setup

Fig. 1 shows the experimental set-up developed: it consists in a passive commercial recumbent trike (ICE VTX™ 2017 - www.icetrikes.com) which has been adapted for use by paraplegic cyclists, in conjunction with FES of the paralyzed muscles of the lower limbs.

Figure 1: *The FES-bike prototype used to participate to CYBATHLON 2020 by the POLIMIRehaMove team.*

The pedals have been replaced by two ankle-foot orthoses from BerkelBike™ (www.BerkelBike.com) to keep the movement of the legs in the sagittal plane. A sensorized smart trainer from Wahoo Fitness™ (www.wahoofitness.com/kickr) was mounted in place of the back wheel. A magnetic encoder (AksIM™ off-axis rotary absolute encoder - www.rls.si/aksimr) has been placed at the crank to measure the crank angle in real-time. On the basis of the actual value of the crank angle, the different muscles groups of the lower limb (i.e. quadriceps, gluteal muscles, hamstrings and gastrocnemius) are stimulated using two commercially available four-channels current-controlled stimulators, RehaMove3™ from Hasomed,GmbH, Germany (www.hasomed.de/rehamove). The stimulators are located in two custom-made housings under the seat. The user interface includes three LEDs showing the status of the system and a LCD display (Kuman 3.5 inches touch screen) both controlled via an Arduino Mega 2560. Four push-buttons allow the pilot to start and stop the stimulation and to increase or decrease the stimulation intensity. The embedded control system is enclosed in a small gray box attached on the back of the seat. It comprises a BeagleBone Black (www.beagleboard.org), a custom-made printed circuit board and a buck DC-DC component (XL6009 DC-DC). All the electronic components are powered through an Anker™ powerbank (AK-A1263011 model) whilst the stimulators are endowed with their own rechargeable battery. The control system runs on the BeagleBone Black using MATLAB/Simulink® Real-time toolbox in external mode.

Pilot

The pilot is 39 years old, 175 cm tall and weighs 70 kg. He is paraplegic (lesion level T5-T6) due to a bike accident occurred in March 2019 and he has an ASIA impairment scale score of A (complete loss of motor and sensory function - www.sci-info-pages.com/levels.html)

Stimulation strategy and parameters

The execution of the cycling movement on the trike required the stimulation of four muscles for each leg: quadriceps, gluteal muscles, hamstrings and gastrocnemius. The precise activation angles of the four muscles were set starting from a previous study carried out on healthy subjects who were asked to pedal on the trike while measures of the EMG activities of the same muscle groups were taken. The resulting stimulation angular ranges were optimized on the pilot through a trial and error procedure.

PALS® reusable electrode from Axelgaard Manufacturing.Co. were used to deliver the current pulses to the muscle groups. The waveform of the pulses was rectangular biphasic, completely balanced in terms of charge.

Participation in CYBATHLON 2020

Training sessions

The pilot was trained on the trike twice a week almost every week from the 29th of September to the 11th of November for a total of ten training sessions. The first sessions were spent optimizing the stimulation angular ranges and the values of current amplitude for each muscle. The remaining training session were organized to resemble the day of the FES-bike race. Three eight minutes trials were performed at every training session, attempting to cover the greater distance.

Case study

Experimental protocol

The four stimulation strategies tested in the case study were:

1. Stimulation with constant frequency trains at 30 Hz.
2. Stimulation with constant frequency trains at 40 Hz.
3. Stimulation with DFTs with an inter-pulse interval of 5.8 ms and an inter-doublets interval of 50 ms, i.e. two closely spaced impulses sent with a frequency of 20 Hz.
4. SDSS on the quadriceps, with a single electrode placed proximally and four smaller electrodes placed distally. The electrical pulses are sent in sequence to the small electrodes, with each small electrode active at 10 Hz, whilst the overall stimulation frequency is 40 Hz.

To assure a fair comparison between the stimulation strategies during cycling the workrate was kept constant. Thus, the resistance of the smart trainer, the gears of the

trike and the cadence were fixed for all sessions and trials. To keep the cadence constant, a closed loop control over the stimulation amplitude (with a saturation limit of 120 mA) was implemented, using a discrete time Proportianal-Integral (PI) controller. The cadence was kept at 35 RPM until saturation was reached. The experimental protocol consisted of 12 testing sessions: during each session, the four stimulation strategies were tested in a randomized order in consecutive trials, with 5 minutes of rest between them. Each trial was stopped one minute after reaching saturation, or after 15 minutes from the beginning of the stimulation. If in the minute after saturation the cadence dropped under 15 RPM, the trial was stopped.
At least 24 hours of rest between consecutive testing sessions were required.
The initial value of current amplitude for the trials was set at 60 mA for quadriceps, gluteal muscles and hamstrings while for the gastrocnemius it was set at 55 mA. The saturation is set to 120 mA for all the muscle groups except the gastrocnemius for which 115 mA is choosen. All the muscles were stimulate with a pulse width of 400 µs.

Once concluded the 12 acquisitions of the experimental protocol, a test trial has been made to verify whether the level of training was increased in the two months of the study. This final trial lasted 8 minutes, in which the pilot tried to reach the same target distance of 1200 m of the FES-bike race.

Outcome measures and statistical analysis

The outcome measures to evaluate fatigue were the saturation time T_{sat} (namely the time elapsed from the beginning of the stimulation, until 120 mA current amplitude is reached) and the root mean square error (RMSE) of the cadence. The distance covered before reaching saturation and in the minute after saturation were also computed. The statistical analysis was carried out using the Kruskal-Wallis test. If a significant difference was found, a post-hoc analysis with Bonferroni correction was carried out.

RESULTS

Participation in CYBATHLON 2020

The initial stimulation parameters for the day of the race were choosen accordingly to the observations made during the trainings. In particular the initial value of current amplitude was set at 70 mA, while the pulse width was set at 400 µs and the stimulation frequency at 30 Hz. The strategy developed aimed at covering the greater possible distance in the first minute, exploiting an high back gear (nine). After the initial boost produced by the fresh muscles, to limit the drop in power output, the pilot was supposed to increment the current, using one of the push button on the handlebar. At minute 4, the pulse width was automatically increased from 400 µs to 500 µs. The value of 100 mA was planned to be reached at around minute 5. In the last two minutes of the race, the objective was to obtain a final sprint, by means of increasing the stimulation frequency to 40 Hz and the current up to the maximum value of 130 mA.

In the final classification of the nine teams that participated in the FES-bike race of CYBATHLON 2020 GLOBAL EDITION, the POLIMIRehamove team has been ranked number seven. The total distance covered in eight minutes was 850m, corresponding to an average linear speed of 6.4 km/h.

Case study

In Fig. 2, it is possible to see the boxplot of the saturation time with respect to the stimulation strategy. The value of T_{sat} for SDSS resulted to be statistically lower with respect both to stimulation at constant frequency of 30 Hz (p-Value 0 0.014) and to stimulation at constant frequency of 40 Hz (p-Value = 0.021). A marked difference between the values of SDSS and DFTs is visually observable from the boxplot, with the median of DFTs higher than the one of SDSS, but no significant differences were observed. In Fig. 2 are displayed also the results of the statistical analysis of the root mean square error of the cadence with respect to the stimulation strategy. No statistically significance could be found. Nevertheless, it is possible to see that the median value of RMSE for SDSS results to be higher compared to the other strategies.

In the final trial, executed after the 12 acquisitions of the case study, the pilot was able to reach the target distance of 1200 m of the FES-bike race in eight minutes.

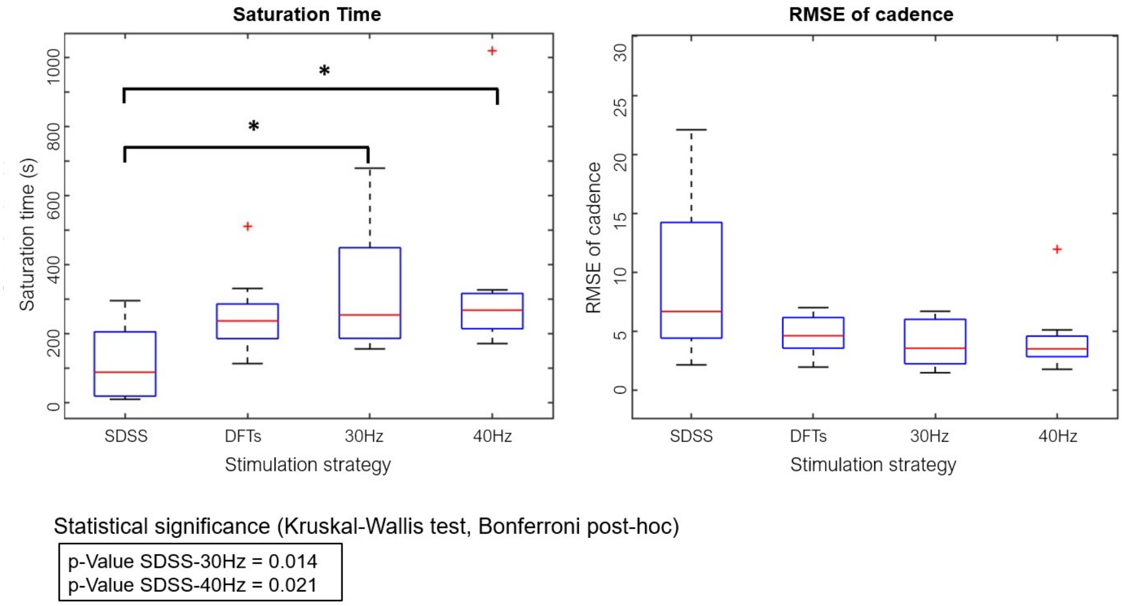

Figure 2: *Boxplots of the saturation time and of the RMSE of the cadence with respect to the stimulation strategies. The saturation time for SDSS results statistically lower when compared to the saturation times of constant frequency of 30 Hz and constant frequency of 40 Hz.*

DISCUSSION

For what concerns the first objective of this work, i.e. the participation at CYBATHLON 2020 GLOBAL EDITION, it can be said that the performance obtained in the FES-bike race was not optimal, since the pilot was not able to cover the target distance of 1200 in the eight minute provided. Still, considering that the time available for training had been dramatically limited due to the Covid-19 pandemic, the covering of 850 m in 8 minutes is impressing, as it means an average linear distance of 6.4 Km/h.

For what concerns the case study, its aim was to investigate the influence of different stimulation strategies on the performance obtained during a FES-cycling task, in terms of muscle fatigue. The results of the 12 acquisitions evidenced a significantly lower performance for SDSS as compared to the other three stimulation strategies. Notably, the values of saturation time for SDSS resulted to be significantly smaller with respect to the stimulation at constant frequency of 30 Hz and 40 Hz. The values of T_{sat} for SDSS were visually lower also compared to DFTs. The RMSE of the cadence was markedly higher for the SDSS, although no statistical significance was found. The quality of the muscle contractions induced by SDSS was visually worse as compared with the other stimulation strategies, as it seemed not totally tetanic, resulting in a less smooth pedalling movement.

These findings are in contrast with some recent studies on SDSS [39, 40, 8] that evidenced a positive effect of the distributed stimulation in reducing muscle fatigue. Two of these studies, namely the one conducted by Maleşević et al. [39] and the one conducted by Nguyen et al. [40] tested SDSS during isometric contractions. Thus, the conclusions drawn in these study cannot be directly transferred to a dynamic task, such as cycling. Furthermore, in [40] SDSS was applied to the gastrocnemius muscle. Although the dynamic knee extension task described in [8] could be compared to FES-induced cycling, the intensities of the stimulation used by Laubacher et al. in [8] are much lower than the ones required for overcoming rough surfaces and inclines in outdoor cycling. In January 2021 Schmoll et al. [43] published a study in which they compared different electrode configurations for SDSS with the conventional two electrodes configuration. The task analyzed consisted of isokinetic contractions of the quadriceps similar to the one described by Laubacher et al. in [8]. The results of the Schmoll's study didn't demonstrate a remarkable effect in fatigue reduction for any of the tested SDSS configuration. Differently from [8], in the study conducted by Schmoll et al. [43] the stimulation amplitudes used to carry out the tests were considerably higher and comparable to the ones used in the present study. The Authors hypothesized that the use of higher stimulation amplitudes in SDSS could cause a certain degree of spillover, leading to the recruitment of additional motor-units indented to be stimulated by a neighboring electrode. Therefore, they concluded that the effects of SDSS could be less pronounced at higher stimulation as a result of the loss of intra-muscular selectivity.

There is the possibility that the low performance of SDSS seen in the present study could be related to the spill-over phenomenon hypothesized by Schmoll et al. On the other hand, Schmoll et al. didn't report a lower performance for SDSS, just a performance similar to the one obtained with conventional single electrode stimulation. Another highly relevant element to be taken into account is electrode placement. We splitted the distal electrodes and in order to minimize the spill-over phenomenon we place the small electrodes relatively distant to each other. This might have caused the quadriceps to not reach a complete tetanic contraction, reducing the produced power at same stimulation amplitudes and and lowering the overall performance of SDSS. Probably to obtain a real advantage from SDSS the electrodes must be sufficiently distant to recruit different motor fibers, even when high values of currents cause some spillover. At the same time the electrodes must be close enough to guarantee a contraction that is completely tetanic.

Conclusions and future developments

The case study presented here demonstrated a lower performance of SDSS compared to the other stimulation strategies tested (DFTs, fixed frequency of 30 Hz and fixed frequency of 40 Hz) during a protocol of FES-cycling. These conclusions are of high relevance since no previous study can be found that analyzes SDSS performance in a dynamic cycling movement. The main two limitations of the study are the presence of a single subject, and the lack of an accurate measurement of the produced torque, which could have given a more direct indication of the cycling performance and of the stimulation efficiency.

In the present study the electrodes for SDSS testing have been placed distally and markedly distant to each other and this could have influenced the bad performance of SDSS. With the aim to further investigate the influence of electrode placement on the efficiency of SDSS in reducing muscle fatigue, other 12 acquisitions are going to be made using a different electrodes configuration for the SDSS strategy. Notably, the four small electrodes are going to be placed proximally on the quadriceps instead of distally and they are going to be placed closer to each other, with the aim to improve the smoothness of the cycling movement and the quality of muscle contractions.

Besides the fatigue reducing effect of the different stimulation strategies tested in the present study, another factor that is crucial in overcoming the rapid fatigue problem of FES applications, and in particular of FES-cycling, is regular training over long periods of time. This has been proven by the fact that the pilot, after participating in the acquisitions for the case study twice a week for two months, was finally able to reach the distance 1200m of the CYBATHLON competition in eight minutes.

Sommario

INTRODUZIONE

La stimolazione elettrica funzionale in soggetti con lesione spinale

Una lesione spinale (Spinal Cord Injury o SCI) è un'interruzione delle fibre motorie discendenti dalla corteccia motoria fino al motoneurone spinale e delle fibre somatosensoriali ascendenti dal midollo spinale alla corteccia cerebrale. I circuiti nervosi al di sotto del livello della lesione possono rimanere intatti ma hanno perso la connessione alla corteccia, pertanto non possono essere attivati dal controllo volontario [1]. Il termine Stimolazione Elettrica Funzionale (in inglese Functional Electrical Stimulation, FES) si riferisce alla stimolazione di un motoneurone intatto per attivare muscoli plegici o paretici con un ordine e un'intensità ben precisi con l'obiettivo di compiere direttamente un'attività funzionale o supportare il suo compimento [2]. Quando la FES viene utilizzata regolarmente per un lungo periodo di tempo, essa risulta efficace nel prevenire molte delle complicazioni secondarie comuni nei soggetti con SCI, come per esempio l'accumulo di sangue negli arti inferiori, la bassa pressione sanguigna e la trombosi venosa profonda [3, 4, 5]. Altri benefici di un allenamento regolare con la FES riguardano il miglioramento della densità minerale ossea e l'aumento della forza muscolare [6, 7], che si traducono anche in una riduzione del rischio di comparsa di piaghe e del rischio di fratture [8]. L'allenamento con la FES ha dimostrato inoltre di migliorare la capacità cardiorespiratoria [9] e di ridurre l'atrofia muscolare [10, 11] e la spasticità [12, 13]. Infine i soggetti con SCI che hanno intrapreso un percorso di allenamento con la FES hanno segnalato anche benefici dal punto di vista psico-sociale [4].

Pedalare grazie alla stimolazione elettrica funzionale

Nella prima metà degli anni '80 per le prime volte fu impiegata la FES per per riprodurre il movimento delle gambe durante la pedalata. Per ottenere questo movimento, alcuni grandi gruppi muscloari delle gambe (tipicamente i quadricipiti, gli hamstrings e i glutei) venivano attivati in modo sequenziale. La maggior parte degli studi eseguiti sull'argomento utilizza cicloergometri stazionari, tuttavia sono stati proposti anche dei dispositivi mobili [14, 15, 16, 17], aprendo alla possibilità di rendere la pedalata indotta dalla FES un'attività ricreazionale da svolgere anche all'aperto [18]. Questo è un aspetto interessante in quanto le persone con SCI dopo la lesione vedono la loro vita quotidiana completamente modificata, con una riduzione dell'attività fisica e una grande necessità di assitenza. Ciò li sottopone anche al rischio di sviluppare forme depressive e, in generale, causa un peggioramento delle condizioni psicologiche [19]. Da qui l'importanza di sviluppare un piano di esercizio fisico, che possa essere efficace ma anche piacevole e divertente per queste persone [20]. Ad oggi, una delle limitazioni principali alla diffusione di dispositivi per la pedalata indotta dalla FES in esterno è la bassa efficienza, intesa come il rapporto tra il lavoro prodotto e l'energia metabolica consumata. L'efficienza della pedalata indotta dalla FES è molto più bassa di quella sviluappata dalla pedalata generata dal controllo volontario. Pertanto uno degli obiettivi più importanti è aumentare l'efficienza della pedalata [18], per arrivare a produrre una potenza sufficiente per superare l'attrito generato dalle superfici ruvide, la resistenza del vento e le pendenze (al momento il valore di potenza sviluppato, ovvero circa 25 W, non lo permette) [20]. L'altro fattore significativo che limita l'utilizzo e l'efficacia di tutte le applicaioni della FES è il problema molto noto in letteratura dell'affaticamento muscolare precoce [8].

Il problema dell'affaticamento precoce nelle applicazioni della FES

E' dimostrato che la velocità di affaticamento dei muscoli durante la FES è molto maggiore rispetto che nel movimento volontario [21]. Uno dei fattori che contribuisce a questo fenomeno è il reclutamento sincrono delle fibre muscolari: quando viene applicata la FES, tutte le unità motorie sono attivate contemporaneamente, a differenza di ciò che accade nella contrazione volontaria, durante la quale il sistema nervoso attiva a rotazione le diverse unità motorie (reclutamento asincrono). Per questo motivo, per raggiungere una contrazione tetanica con la FES, è necessaria una frequenza di stimolazione maggiore (dai 20 Hz ai 40 Hz) che causa un affaticamento precoce delle fibre muscolari [22, 21]. In aggiunta, la FES recluta prima le unità motorie veloci e affaticabili (fast-twitch fatiguable, FF), rispetto a quelle lente e resistenti alla fatica (slow-twitch, S). Infine i muscoli paralizzati sono soggetti ad atrofia da disuso e a cambiamenti istochimici che provocano una conversione delle fibre verso la tipologia veloce e facilmente affaticabile [23].

Strategie di stimolazione per contrastare l'affaticamento precoce

Molti studi hanno analizzato l'effetto di diversi pattern di stimolazione sulla forza prodotta dalla contrazione muscolare e sulla fatica neuromuscolare. I principali pattern di stimolazione analizzati sono quelli a frequenza costante (Constant Frequency Trains, CFTs), quelli a frequenza variabile (Variable Frequency Trains, VFTs) e quelli con doppietti (Doublet Frequency Trains, DFT) [24, 25, 26, 27, 27, 28]. Solitamente, la FES usa CTFs, ovvero pattern in cui gli impulsi di corrente sono separati da intervalli di tempo regolari [29]. I VFTs sono invece treni di impulsi separati da intervalli di tempo regolari, ma caratterizzadi da un doppietto iniziale (cioè da una coppia di impulsi ravvicinati, tipicamente mandati con 5-10 μs di distanza) [30]. Infine nei DFTs delle coppie di impulsi (doppietti distanziati da un intervallo inter-impulso di circa 5 ms) sono separati da intervalli di tempo maggiori (intervallo inter-doppietto) [31]. VFTs e DFTs sfruttano la sommazione non lineare della forza [32] e la catch-like property delle fibre muscolari [33].

Comunemente, per attivare un muscolo con la FES, si posizionano sul muscolo stesso due elettrodi che inducono la contrazione simultanea di tutte le fibre reclutate [34]. Dal momento che una delle cause dell'affaticamento precoce dei muscoli durante la FES è l'attivazione simultanea di solo un sottogruppo di fibre, si è pensato di testare delle configurazioni con elettrodi multipli, nelle quali gli elettrodi sono più di due, consentendo l'attivazione di un numero maggiore di unità motorie all'interno dello stesso gruppo muscolare. Questa strategia di stimolazione consiste nell'invio di impulsi di corrente, in modo sequenziale, ad un elettrodo dopo l'altro e viene detta stimolazione sequenziale distribuita nello spazio (Spatially Distributed Sequential Stimulation, SDSS). Durante la SDSS il muscolo raggiunge il tetano fuso nonostante ciascun elettrodo sia attivato ad una frequenza sub-tetanica [40].

CYBATHLON

Il CYBATHLON è una competizione organizzata dall'ETH di Zurigo, all'interno della quale persone con disabilità fisica competono in discipline che ocinvolgono azioni di vita quotidiana, eseguite grazie all'ausilio di sistemi tecnologici di assistenza di ultima generazione. L'edizione globale di CYBATHLON 2020 si è tenuta il giorno 13 Novembre 2020 in modalità remota a causa della pandemia da Covid-19. Tra le diverse discipline di CYBATHLON 2020 è compresa una gara di FES-bike che coinvolge piloti con lesione spinale completa. I partecipanti alla disciplina devono coprire una distanza di 1200 m in 8 minuti, pedalando con l'ausilio della FES su un trike passivo opportunamente adattato per lo scopo [42].

Obiettivi

Questo lavoro di tesi magistrale si pone due obiettivi principali:

1. L'ottimizzazione del prototipo di FES-bike per piloti paraplegici, da utilizzare durante la partecipazione all'edizione globale di CYBATHLON 2020. L'ordanizzazione e la supervisione delle sessioni di allenamento del pilota e la determinazione dei parametri ottimali di stimolazione per la gara.

2. La progettazione di un caso studio basato sull'esperienza di CYBATHLON che permetta di confrontare diverse strategie di stimolazione (a frequenza costante, DFTs e SDSS) in termini di affaticamento muscolare durante la pedalata. In particolare questo caso studio viene sviluppato con l'intento di supplire alla mancanza di studi precedenti che condrontino gli effetti di DFTs e SDSS direttamente nella pedalata.

MATERIALI E METODI

Setup sperimentale

La Fig. 3 mostra il setup sperimentale di questo studio, che consiste in un trike reclinato commerciale, completamente passivo (ICE VTX™ 2017 - www.icetrikes.com), che è stato adattato per l'utilizzo da parte di ciclisti paraplegici grazie all'integrazione della FES per gli arti inferiori.

Figura 3: *Il prototipo di FES-bike usato per partecipare a CYBATHLON 2020 dalla squadra POLIMIRehaMove.*

I pedali sono stati sostituiti da due ortesi caviglia-piede prodotte da BerkelBike™ (www.BerkelBike.com), necessarie per assicurare che il movimento delle gambe rimanga sul piano sagittale. Uno smart trainer sensorizzato prodotto da Wahoo Fitness™ (www.wahoofitness.com/kickr) è stato montato al posto della ruota posteriore. Un encoder magnetico (AksIM™ off-axis rotary absolute encoder - www.rls.si/aksimr) è stato posizionato alla pedivella per misurare la posizione angolare dei pedali in tempo reale. Sulla base dell'angolo misurato, i diversi gruppi muscolari delle gambe (quadricipiti, glutei, hamstrings e gastrocnemi) sono sitmolati utilizzando due stimolatori commerciali a 4 canali RehaMove3™ (Hasomed,GmbH, Germany-www.hasomed.de/rehamove). Gli stimolatori sono posizionati sotto al sedile del trike in due alloggiamenti stampati in 3D. L'interfaccia utente comprende tre LED che segnalano lo stato del sistema e un display LCD (Kuman 3.5 inches touch screen) che fornisce informazioni sui parametri di stimolazione e la performance. Entrambi sono controllati grazie ad un Arduino Mega 2560 e sono alloggiati di fronte al pilota. Quattro pulsanti consento al pilota di far partire e interrompere la stimolazione e di incrementarne o decrementarne l'intensità.

Il sistema di controllo integrato è racchiuso in una piccola scatola grigia che è fissata nella zona posteriore del sedile. Il sistema di controllo comprende una BeagleBone Black (www.beagleboard.org), un circuito stampato e un componenet buck DC-DC (XL6009 DC-DC). Tutta l'elettronica è alimentata attraverso un powerbank Anker™ (AK-A1263011 model), mentre gli stimolatori sono dotati di una propria batteria ricaricabile. Il programma di controllo real-time viene eseguito sulla BeagleBone Black utilizzano il toolbox Real-time di MATLAB/Simulink®

Pilota

Il pilota ha 39 anni, è alto 175 cm e pesa 70 kg. E' paraplegico a causa di un incidente in bicicletta avvenuto nel Marzo del 2019. Il livello della lesione è T5-T6 e il punteggio nella scala ASIA di valutazione del danno neurologico è A, cioè completa pedita delle funzioni motoria e sensoriale (www.sci-info-pages.com/levels.html).

Strategia di stimolazione

L'esecuzione del movimento di pedalata sul trike richiede l'utilizzo di quattro gruppi muscolari per ogni gamba: quadricipiti, hamstrings, glutei e gastrocnemio. Il range preciso di attivazione di ciascun muscolo è stato deciso a partire da uno studio precedentemente realizzato su soggetti sani, che ha permesso di registrare i segnali EMG dei muscoli delle gambe durante la pedalata sul trike. I valori sono stati poi adattati al pilota attraverso una procedura di trial and error. Per la stimolazione sono stati usati gli elettrodi riutilizzabili PALS® (Axelgaard Manufacturing.Co) e sono stati utilizzati impulsi con forma d'onda rettangolare bifasica, che prevede un bilanciamento completo della carica.

Partecipazione a CYBATHLON 2020

Sessioni di allenamento

Il pilota è stato allenato sul trike due volte a settimana, quasi ogni settimana, dal 29 di Settembre all'11 di Novembre, per un totale di 10 allenamenti. Le prime sessioni sono state dedicate all'ottimizzazione dei range e dei parametri di stimolazione per ogni muscolo. I rimanenti allenamenti sono stati organizzati in modo molto simile al giorno della gara, con tre tranches di stimolazione della durata di 8 minuti, durante le quali il pilota cercava di coprire la maggiore distanza possibile.

Caso studio

Protocollo sperimentale

Le quattro strategie di stimolazione testate nel caso studio sono:

1. Stimolazione a frequenza costante di 30 Hz
2. Stimolazione a frequenza costante di 40 Hz
3. Stimolazione con DFTs con un intervallo inter-impulso di 5.8 ms e un intervallo inter-doppietto di 50 ms. Cioè le coppie di impulsi ravvicinati sono mandati con una frequenza di 20 Hz
4. SDSS sui quadricipiti, con un elettrodo singolo posizionato prossimalmente e quattro elettrodi più piccoli posizionati distalmente. Gli impulsi di corrente sono distribuiti sequenzialmente ai singoli elettrodi, in modo che siascuno di essi è attivato a 10 Hz, ma la frequenza complessiva ricevuta dal muscolo è 40 Hz.

Per realizzare un corretto confronto delle diverse strategie di stimolazione, è stato realizzato un controllo in anello chiuso che garantisce una pedalata a cadenza costante di 35 rpm. La resistenza dello smart trainer e il cambio della bicicletta sono stati mantenuti fissi durante ogni test, in modo da assicurare un work-rate costante. Il controllo è stato implementato utilizzando un controllore PI (Proporzionale Integrativo) che regola in egual misura l'ampiezza di corrente degli stimoli inviati a tutti i diversi gruppi muscolari (con un limite di saturazione impostato a 120 mA per i quadricipiti, gli hamstrings e i glutei e a 115 mA per i gastrocnemi). Il protocollo di test prevede 12 sessioni, nelle quali tutte le quattro strategie di stimolazione vengono testate in ordine randomico, durante quattro diverse prove. Almeno 24 ore devono intercorrere tra una sessione e la successiva. Ciascuna delle quattro prove di una sessione viene interrotta un minuto dopo il raggiungimento del limite di saturazione o al superamentodi 15 minuti complessivi di stimolazione. Qualora nel minuto successivo alla saturazione la cadenza scenda sotto 15 rpm, la prova è interrotta con anticipo. Tra le quattro prove di una sessione sono previsti 5 minuti di pausa. In **??** sono riportati i parametri di stimolazione utilizzati durante le sessioni di test. I valori iniziali di intensità di corrente utilizzati per le prove sono di 60 mA per i quadricipiti, i glutei e gli hamstrings, e di 55 mA per il gastrocnemio. I valori di saturazione sono stati settati a 120 mA per tutti i gruppi muscolari eccetto il gastrocnemio per il quale la saturazione è prevista a 115 mA. La pulse width è stata regolata a 400 µs per tutti i gruppi muscolari.

Una volta concluse le 12 acquisiszioni del protocollo sperimentale, un ultima prova è stata eseguita con l'intento di verificare se nei due mesi di acquisizioni il livello di allenamento del pilota era migliorato. L'obiettivo di questa prova finale era cercare di raggiungere in 8 minuti la distanza di 1200 m prevista dalla gara di FES-bike.

Statistical analysis of the outcome measures

Le misure utilizzate per valutare l'affaticamento muscolare sono il tempo di saturazione T_{sat} (cioè il tempo intercorso dall'inizio della stimolazione fino al raggiungimento del valore massimo di ampiezza di 120 mA) e lo scarto quadratico medio della cadenza dal valore target di 35 rpm (Root Mean Square Error o RMSE). Sono state calcolate anche le distanze percorse fino al raggiungimento di saturazione e nel minuto successivo alla saturazione. L'analisi statistica è stata eseguita utilizzando il test di kruskal-Wallis. Il metodo di Bonferroni è stato impiegato per effettuare l'analisi pot-hoc su tutte le differenze significative riscontrate.

RISULTATI

Partecipazione a CYBATHLON 2020

I parametri iniziali di stimolazione per il giorno della gara sono stati decisi basandosi sulle osservazioni fatte durante gli allenamenti e prevedevano di settare l'intensità di corrente a 70 mA, la pulse width a 400 µs e la frequenza di stimolazione a 30 Hz.

La strategia è stata elaborata con l'intento di cercare di coprire la maggiore distanza possibile nel primo minuto di stimolazione, durante il quale i muscoli ancora riposati sviluppano una grande forza. Per questo motivo si è scelto di partire da un valore elevato di marcia posteriore (nove). Quando il boost iniziale si conclude, il pilota deve incrementare manualmente la corrente utilizzando i pulsanti sul manubrio, in modo da contrastare la diminuzione di potenza. Al minuto 4 la pulse width viene incrementata in modo automatico da 400 µs a 500 µs. Il valore di 100 mA di intensità di corrente deve essere raggiunto attorno ai 5 minuti. Inoltre negli ultimi due minuti la frequenza di stimolazione deve essere aumentata a 40 Hz e la corrente deve essere incrementata fino al raggiungimento del valore massimo di 130 mA nel tentativo di realizzare uno sprint finale.

La classifica finale della competizione di FES-bike dell'edizione globale di CYBATHLON 2020 vede il team POLIMIRehaMove classificato come settimo su nove squadre partecipanti. La distanza percorsa dal pilota in 8 minuti è stat di 850 m, con una velocità media di 6.4 km/h.

Caso studio

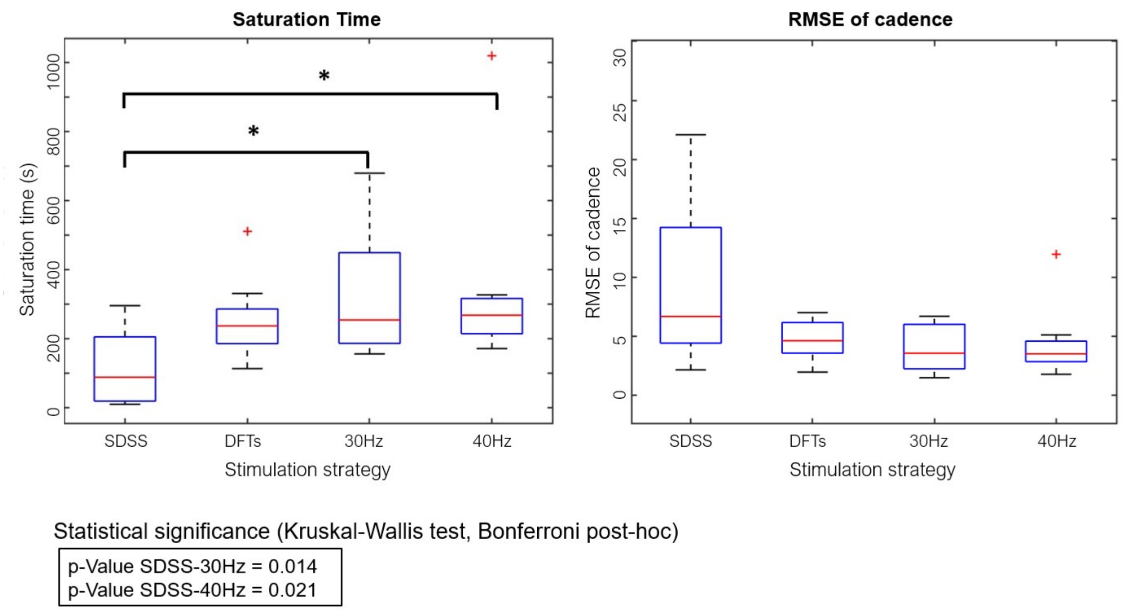

Figura 4: *Boxplot del tempo di saturazione rispetto alle strategie di stimolazione. Il tempo di saturazione per SDSS risulta statisticamente inferiore riespetto alla stimolazione a 30 Hz costanti e 40 Hz costanti*

In Fig. 4 è riportato il boxplot del tempo di saturazione rispetto alla strategia di stimolazione. I valori di T_{sat} per SDSS risultano statisticamente inferiori rispetto sia alla stimolazione a frequenza costante di 30 hz (p-Value 0.014) sia rispetto alla stimolazione a frequenza costante di 40 Hz (p-Value= 0.021). Dal boxplot è anche possibile evidenziare una differenza consistente tra i valori di SDSS e quelli di DFTs con la mediana di DFTs superiore a quella di SDSS. Sempre in **??** è riportato anche il boxplot dello scarto quadratico medio della cadenza rispetto al valore target di 35 rpm. Non è presente alcuna differenza statisticamente significativa tra le diverse strategie di stimolazione, tuttavia è possibile notare come la mediana per SDSS sia visivamente maggiore rispetto alle altre strategie di stimolazione.

Nella prova finale, eseguita al termine delle 12 acquisizioni necessarie per il caso studio, il pilota è stao in grado di raggiungere il traguardo di 1200 m in 8 minuti.

DISCUSSIONE

Per quanto riguarda il primo obiettivo della tesi, cioè la partecipazione all'edizione globale id CYBATHLON 2020, si può dire che la performance ottenuta non è stata ottimale, in quanto il pilota non è stato in grado di raggiungere il traguardo di 1200 m negli 8 minuti previsti. Tuttavia, se si considera che lo scoppio della pandemia da Covid-19 ha ridotto di moltissimo il tempo a disposizione per l'allenamento del pilota, il fatto che negli 8 minuti della gara sia stato in grado di coprire una distanza di 850 m è comunque notevole dal momento che implica il mantenimento di una velocità lineare media di 6.4 Km/h.

Per quanto riguarda il caso studio, esso si poneva l'obiettivo di analizzare l'influenza di diverse strategie di stimolazione sull'affaticamento muscolare sviluppato durante un task di pedalata indotta dalla FES. Il risultato delle 12 acquisizioni effettuate evidenzia una significativa differenza nella performance di pedalata ottenuta in particolare con SDSS rispetto alle altre strategie di stimolazione. In particolare, il tempo di saturazione per SDSS risulta significativamente minore rispetto alla stimolazione a 30 Hz costanti e a 40 Hz constanti, e visivamente è possibile notare che la sua mediana è inferiore anche rispetto a DFTs. Lo scarto quadratico medio della cadenza è marcatamente più alto per SDSS, rispetto alle altre strategie, anche se nessuna significtività statistica è stata rilevata. Tuttavia, la qualità della contrazione muscolare indotta da SDSS è risultata visivamente peggiore delle altre strategie in tutte le prove, con i quadicipiti che non sembravano riuscire a raggiungere la completa fusione della contrazione e la pedalata che era di conseguenza poco fluida.

Questi risultati sono in contrasto con quelli ottenuti in alcuni recenti studi su SDSS [39, 40, 8] che hanno evidenziato un effetto positivo di SDSS nella riduzione dell'affaticamento muscolare precoce. Va però notato che due di questi studi, cioè quello condotto da Maleşević et al. [39] e quello eseguito da Nguyen et al. [40] hanno analizzato l'effetto di SDSS durante una contrazione isometrica; pertanto le conclusioni tratte in questi studi sono difficili da applicare a un task dinamico di pedalata, come quello presentato qui. Inoltre in [40] SDSS non è stata testata sul quadricipite ma bensì sul gastrocnemio. Il task di estensione isocinetica del ginocchio presentato in [8] da Luabacher et al. può essere considerato simile al movimento della pedalata, tuttavia le intensità di stimolazione utilizzate in [8] sono nettamente inferiori a quelle necessarie per pedalare in esterno. Nel Gennaio 2021 Schmoll et al. [43] hanno pubblicato uno studio in cui sono state paragonate la stimolazione convenzionale con due elettrodi e la stimolazione SDSS eseguita con diverse configurazioni di elettrodi, durante un task di estensione isocinetica del ginocchio. I risultati di questo studio non hanno dimostrato nessun impatto significativo sull'affaticamento precoce per nessuna delle configurazioni testate per SDSS. La differenza rispetto a [43] risiede nell'utilizzo di intenistà di stimolazione molto maggiori (quindi più simili a quelle necessarie per la pedalata in esterno). Schmoll et al. hanno ipotizzato che l'utilizzo di elevate intensità di stimolazione possa causare un certo grado di spill-over, causando il reclutamento di unità motorie che dovecano essere attivate da altri elettrodi in momenti successivi. Pertanto gli Autori hanno conclusio che l'effetto di SDSS possa essere reso meno efficace dall'utlizzo di elevate intensità di stimolazione a causa di una pedita di selettività intra-muscolare.

C'è la possibilità che la bassa performance di SDSS rilevata nel caso studio presentato qui, possa essere dovuta la fenomeno di spill-over descritto da Schmoll et al. in [43], tuttavia Schmoll et al. hanno riscontrato una performance simile tra SDSS e stimolazione convenzionale, non un peggioramento della performance con SDSS, perciò è possibile che ci siano altri fattori da tenere in considerazione.

Certamente un elemento che ha una grande influenza è il posizionamento degli elettrodi per testare SDSS. Nello studio presentato qui gli elettrodi utilizzati per SDSS sono statu posizionati in modo alquanto distanziato l'uno dagli altri. Questo potrebbe aver impedito ai quadricipiti di raggiungere una contrazione pienamente tetanica durante le prove e aver conseguentemente inficiato la performance rilevata.

Probabilmente per ottenere un vero vantaggio da SDSS è necessario individuare una precisa configurazione degli elettrodi che li vede sufficientemente distanti per contrastare il fenomeno di spill-over anche ad elevate intensità, ma allo stesso tempo sufficientemente vicni da garantire sempre una contrazione completamente tetanica dei muscoli.

Conclusioni e sviluppi futuri

Il caso studio presentato qui ha dimostrato una peggiore performance di SDSS nel confronto con le altre strategie di stimolazione (DFTs, stimolazione a frequenza fissa di 30 Hz e 40 Hz) eseguito durante un task di pedalata indotta dalla FES. Queste conclusioni sono particolarmente significative, in quanto ad oggi non è possibile trovare in letteratura uno studio precedente che analizzi la performance di SDSS direttamente durante un movimento dinamico di pedalata. Le principali limitazioni dello studio sono la presenza di un singolo soggetto e l'assenza di una misura diretta della forza esercitata al pedale, che avrebbe garantito delle misure più dirette della performance e dell'efficienza della pedalata.

In questo studio, gli elettrodi per testare SDSS sono stati posizionati distalmente e notevolmente distanti l'uno dall'altro e questo può aver influenzato la bassa performance di SDSS rilevata. Pertanto, altre 12 acquisizioni saranno eseguite con l'obiettivo di fare luce sull'influenza del posizionamento degli elettrodi sull'efficacia di SDSS nel ridurre l'affaticamento muscolare precoce. In particolare le ulteriori 12 acquisizioni saranno eseguite posizionando i quattro elettrodi di dimensioni ridotte per SDSS prossimalmente e in modo più ravvicinato, ma sempre andando a coprire l'intera larghezza del muscolo.

L'impiego di particolari strategie di stimolazione non è l'unico fattore cruciale per diminuire l'affaticamento muscolare precoce nelle applicazioni della FES. Un altro elemento fondamentale è infatti l'allenamento costante per lunghi periodi di tempo che risulta vitale soprattutto in ambiti come la pedalata in esterno. Ciò è stato dimostrato dal fatto che a seguito di due mesi in cui ha partecipato alle acquisizioni per il caso studio regolarmente due volte a settimana, il pilota è stato facilmente in grado di raggiungere la performance di 1200 m percorsi in 8 minuti prevista dalla gara di FES-bike di CYBATHLON 2020.

Chapter 1

Introduction

1.1 Spinal Cord Injury (SCI)

The term "spinal cord injury" (SCI) refers to damage to the spinal cord resulting from trauma or from disease or degeneration. Every year, around the world, between 250'000 and 500'000 people suffer a spinal cord injury. [44]

Symptoms of spinal cord injury depend on the severity of injury and its location in the spinal cord [44] and may include partial or complete loss of sensory function, paralysis, or both to body segments below the level of the injury [22]. In some cases, SCI also disrupts the autonomic nervous system, which regulates visceral functions such as blood pressure, heart rate, body temperature, and digestive processes [22]. Those surviving the initial brunt would suffer from many other associated medical conditions like respiratory infections, urinary tract infections, [1], pressure sores, muscle spasm, cardiovascular disease, and osteoporosis [22]. The life expectancy of people with SCI today is becoming close to that of the normal population, yet for the rest of their lives they remain dependent on others for managing their day to day living [1]. An estimated 20/30% of people with spinal cord injury show clinically significant signs of depression, which in turn has a negative impact on improvements in functioning and overall health. Essential measures for improving the survival, health and participation of people with spinal cord injury include access to appropriate assistive devices that can enable people to perform everyday activities they would not otherwise be able to undertake, reducing functional limitations and dependency [44]. A possible approach towards functional recovery involves the use of electrical stimulation through the neural prosthetic devices for partially restoring the lost functions [1].

1.2 Functional Electrical Stimulation (FES) in subjects with SCI

Spinal cord injury disrupts the descending motor fibers from the motor cortex to the spinal motoneurons, and the ascending somato-sensory fibers from the spinal cord to the brain. The functional loss seen in SCI is due to interruption of electrical impulse conduction through the lesioned axons. Intrinsic circuits below the level of injury remain intact but disconnected from descending controls from the cerebral cortex [1]. The use of electrical stimulation (ES) of the central and peripheral nervous system can take advantage of these intact neuromuscular systems to allow functional restoration, and even to manage or prevent many medical complications following SCI [45].

1.2.1 Basic principles of FES

The term Functional Electrical Stimulation (FES) refers to the stimulation of an intact lower motor neuron to activate plegic or paretic muscles in precise sequence and magnitude so as to directly accomplish or support functional tasks. [2] During FES, a train of current pulses is delivered through a couple of electrodes to specific motor neurons, providing sufficient charge to generate a localized depolarization of the cell wall, resulting in an action potential that propagates toward the end of the axon (orthodromic propagation). Concurrently, an action potential propagates backward towards the cell body (antidromic propagation). [46, 22]. FES substitutes for the normal volitional control and excites nervous fibers and not muscular fibers, because the activation threshold for eliciting a nerve fiber action potential is 100 to 1000 times less than the threshold for muscle fiber stimulation [47]. Current pulses can be mono-phasic, in which a constant current is delivered for a period of time and then the circuit is open, or bi-phasic, in which a constant current is passed in one direction, then the direction of current is reversed. Biphasic pulses are commonly adopted in order to balance the charge delivered to the nerves. [48]

1.2.2 Stimulation parameters

The delivery of electrical stimulation can be customized by adjusting the associated stimulation parameters, displayed in Fig. 1.1:

- Frequency refers to the number of pulses delivered per second and it is measured in Hertz (Hz).
- The time span of a single pulse is known as the pulse width or pulse duration (measured in microseconds, µs).
- The pulse intensity/amplitude is the current magnitude (usually reported in milliamperes, mA).
- The waveform displays the magnitude of current or of voltage with respect to time.
- The duty cycle is the total time to complete an on/off cycle [30],[1].

The product between the amplitude and pulse width defines the charge delivered by each positive or negative pulse and determines the number of muscle fibers that are recruited (spatial summation): greater muscle force generation is accomplished by either increasing the pulse duration or stimulus amplitude to activate fibers with an higher activation threshold (both smaller fibers and fibers at a greater distance from the electrodes). On the other hand, temporal summation is determined by the rate at which stimulus pulses are applied to muscle. The minimum stimulus frequency that generates a fused muscle response is about 12.5 Hz [49].

1.2.3 Electrodes types and placing

The electrodes can be transcutaneous (placed on the skin surface), percutaneous (placed within a muscle), epimysial (placed on the surface of the muscle) or cuff (wrapped around the nerve that innervates the muscle of interest) [22].
When using surface electrodes, the success of the FES current to reach underlying tissue is highly related to electrode size and placement, as well as the conductivity of the skin-electrode interface [50]. Typical surface electrodes used are pre-gelled self-adhesive electrodes to improve the transmission of the current. Larger surface electrodes activate a larger number of motor fibers but disperse the current over a wider surface area, decreasing current density. Smaller electrodes concentrate current densities, with less chance of stimulation crossover into nearby muscles, but with increased chance for tissue damage due to a higher charge density. Placement of electrodes also markedly influence the muscle response and should be carefully considered [30].

1.2.4 The long-term benefits of FES exercise

FES provides a means of mobilising lower limbs in complete paraplegics and has shown to be effective in preventing secondary complications like blood pooling in the lower limbs, low blood pressure and deep venous thrombosis, when used regularly over a period of time [3, 4, 5].
Positive adaptations of bone mineral density and increased muscle strength are further benefits following FES training [6, 7]. These improvements help to reduce the risk of pressure sores and fractures [8].
FES has also demonstrated the capacity of strengthening muscles [51, 52], of improving cardiopulmonary fitness [9], of reducing muscle atrophy [10, 11] and spasticity [12, 13].

Positive psycho-social adaptations have also been reported among SCI individuals who undergo FES exercise [4].

1.3 FES-cycling

In the first half of the 1980s it was established that people with a spinal cord injury are able to produce cyclical leg motion by means of controlled sequential stimulation of the large leg-actuating muscles (typically the quadriceps, hamstrings and gluteal muscle groups). We refer to this as FES-cycling [18].

A number of subsequent investigations have studied the physiological adaptations which can occur in response to regular cycling exercise. Significant improvements in cardiopulmonary status (as indicated by increased peak oxygen uptake and faster oxygen uptake response kinetics) and in tibial bone density have been observed [18]. Other therapeutic and medical benefits demonstrated include the increase of strength, endurance and mass of paralyzed muscle [53], the improvement of lower limb circulation [54] and the increase of range of joint motion [55]. It can be also induced a fiber-type conversion towards more oxidative muscle fibers [56]. While most previous studies have utilized stationary FES-cycling ergometers, a number of mobile devices have been also proposed [14, 15, 16, 17], raising the possibility that FES-cycling might become a recreational activity [18]. All the cited FES-cycling devices share some common features:

- The muscle stimulation is synchronized to the crank angle
- Ankle orthoses are used to avoid plantar- and dorsi-flexion, internal and external rotation and inversion and eversion
- The system has to be simply used by paralyzed patients
- The distance between hip and pedals are individually adjustable for each subject

Electrodes are placed over the target muscles: always over the extensors and flexors of the knee (quadriceps and hamstrings), sometimes over some of the hip extensors (gluteus maximum), the plantar-flexors and dorsi-flexors of the ankle. During FEScycling, the quadriceps contributes most to the total power output, followed by the hamstrings and then the gluteus maximum.

1.3.1 The relevance of outdoor FES-cycling

People with SCI experience a reduction in physical activity and an increased difficulty in the accomplishment of everyday life tasks that make them feel highly dependent upon caregivers. These are some of the reasons why they are also at greater risk of poor mental health including depression [19]. Developing an exercise program that is effective and enjoyable is paramount for this population [20].
Stationary FES-cycling systems are commercially available and have been utilized as an exercise modality, but recipients sometimes grow bored of the mundane routines, resulting in reduced compliance and consequent declines in functional performance. End-users look forward to FES applications which can promote recreational activities. Outdoor recreational cycling for people with SCI consists mainly of hand cycling with a small percentage of the population utilizing a hybrid arm-leg FES-cycling device (e.g. Berkelbike - www.berkelbike.com). Indeed, up to now the technical challenges of FES-induced overground cycling have to be fully resolved yet [20].

1.3.2 Challenges of outdoor FES-cycling

It has been noted that the efficiency of FES-cycling, i.e. the ratio of external work output to metabolic energy input, is much lower than that of able-bodied subjects cycling under volitional control. Therefore, maximization of cycling efficiency is one of the most important aspect for outdoor mobile cycling [18], since the low peak powers induced by FES (approximately 25 W) are not enough to overcome rough surfaces, slight inclines or headwinds [20]. The other major factor that limits the use and effectiveness of FES in all contexts is the well-known problem of the rapid onset of muscle fatigue [8]. In fact, it is observed that the rate of fatigue during electrical stimulation of skeletal muscle is much greater than that seen during volitional contractions [21].

1.4 FES: the problem of muscle fatigue

Muscle fatigue is defined as a decrease in the force-generating ability of a muscle that results from recent muscle activity [57]. Rapid muscle fatigue onset during FES-evoked contractions in individuals with SCI is a significant limitation to attaining health benefits of FES-exercise. Delaying the onset of muscle fatigue is often cited as an important goal linked to FES clinical efficacy [58].
Several factors contribute to the poor efficiency of FES-cycling, and they are the same that accounts for the rapid onset of muscle fatigue.

1.4.1 Differences between physiological and FES-induced muscle contraction

Asynchronous vs. synchronous motor units activation

Each motor neuron, together with the innervated muscle fibers, forms a motor unit [22]. The body achieves a constant tension, known as tetanic contraction, by activating adjacent motor units at a frequency of 6-8 Hz in a sequential manner, so that one motor unit delivers a contractile impulse to its muscle fibers before the adjacent motor unit relaxes from the previous activation impulse [59], as shown in Fig. 1.2.

This method of sustaining a muscle contraction, known as asynchronous recruitment, allows the various motor units to share the work of maintaining a muscle contraction, and ensures that the muscle fatigues slowly, since each motor unit is active only for a portion of the total contraction time [22]. Also, during volitional contractions, the human motor system is able to carry out a turn-over of the fibers, continuously substituting the fatigued one with others, thus delaying the offset of muscle fatigue [30].

On the contrary, FES recruits motor units in a synchronous manner. Synchronous recruitment means that FES stimulates all the motor units at the same time, instead of rotating through the motor units as is done during physiological muscle contractions. For this reason, achieving tetanic contractions induced by FES requires higher stimulation frequency (20-40 Hz) than the frequency required to achieve tetanic contraction with the asynchronous recruitment performed by the intact nervous system (6-8 Hz) [22].

Higher frequencies result in a much more rapid fatigue [21]. Moreover, this simultaneous activation observed during FES-induced muscle contractions can produce sudden, sometimes uncoordinated, inefficient movement patterns rather than the smooth gradation of force typically seen in human movements [30].

Physiological vs. non-physiological motor fibers recruitment order

Individual motor units are homogeneous with respect to their fiber type composition, and may be classified as slow-twitch fatigue resistant (S), fast-twitch fatigue resistant (FR) and fast-twitch fatiguable (FF), with each motor unit type composed of Type I, Type IIa, and Typer IIb fibers, respectively [57].

- Type I fibers use oxidative processes as their primary metabolic mechanism, and they have a high capillary density and an enormous capacity to resist fatigue.
- Type IIb fibers use glycolytic processes as their primary metabolic mechanism, have a low capillary density, and are quickly fatigued.
- Type IIa fibers use both oxidative and glycolytic processes for metabolism, and their capillarization and fatigue responses are more like those of Typer I fibers [57].

In normal human movement, the smaller, fatigue resistant motor units are activated first, following the Hennemann's size principle [60], which helps to delay the onset of fatigue [30]. FES, instead, is believed to recruit the large fast-twitch fatiguable (FF) motor units before the small slow-twitch fatigue resistant (S) motor units. This order of recruitment, known as nonphysiological recruitment, is the opposite of the natural muscle-fiber recruitment order. This happens because the fast-twitch fatiguable (FF) motor units are innervated by axons with a larger diameter that are easier to activate [22, 61]. Although the reversal of the Hennemann's size principle is a commonly reported shortcoming of FES-induced muscle contractions, some have postulated that, rather than an exact reversal of the process, activation may be less systematic or non-selective [62].

Muscle histochemical changes after SCI

Following paralysis, muscles can become weak as a result of disuse atrophy. In addition, histochemical changes occur which result in a shift towards fast-twitch, readily-fatiguable muscle fibers [23].
However, disuse atrophy is often a reversible process since the affected muscles can be retrained with electrically stimulated weight-bearing exercise to increase their strength and fatigue resistance [63].

Spasticity

Paralysed muscle generally displays some degree of spasticity; inappropriate muscle contractions can therefore be induced by the cycling motion or by the externally-applied stimulation [18].

1.4.2 Stimulation strategies to postpone the onset of muscle fatigue in FES applications

The need for practical solutions to the "rapid fatigue problem" is of paramount importance to foster the diffusion of FES applications in the daily life of people with SCI [58]. In particular, to enable FES-cycling to become a recreational activity practiced outdoor on a daily basis it is mandatory to address the main problems of rapid muscle fatigue and low produced power output, in a way to allow SCI subject to pedal for a consistent amount of time.

Different approaches have been proposed in the literature to post-pone the onset of muscle fatigue in FES applications. The effect of the stimulation frequency have been investigated, but also the impact of the delivery of closed spaced couple of pulses instead of single pulses. Moreover, different electrodes set-up have been tested with the aim to "distribute" the stimulation over different muscle fibers, thus reproducing the physiological turn-over of the fibers. All the most important fatigue reducing stimulation strategies are described in the next paragraphs.

Stimulation frequency

Among the different stimulation parameters, frequency seems to have more effects on fatigue than pulse duration or amplitude [64]. Constant, low frequency trains of pulses show better fatigue resistance compared to high frequency trains, but on the other hand the power output is significantly lower [65, 66, 67, 68]. However, there is strong evidence suggesting that the force decay can be expressed as a function of the total number of pulses received, independent of stimulation rate [69].

In a study published by Eser et al. in September 2003 [68], stimulation frequencies of 30 Hz, 50 Hz and 60 Hz were compared during a FES-cycling training lasting 30 minutes with a duty cycle of 1/4. The results of the study demonstrated that a 25% higher power output is achieved by using a stimulation frequency of 60 Hz compared to 30 Hz while muscle fatigue could not be detected at any of the tested frequency.

Stimulation patterns

Several investigations have examined the effects of various stimulation patterns on force output and neuromuscular fatigue. Common stimulation patterns studied are constant frequency trains (CFTs), variable frequency trains (VFTs) and doublet frequency trains (DFTs) [24, 25, 26, 27, 27, 28]. Traditionally, FES uses CTFs, brief stimulation pulses separated by regular interpulse intervals [29]. VFTs are pulse trains that begin with an initial doublet, (two closely spaced pulses, typically 5-10 μs apart) followed by pulses at a chosen frequency [30], while in DFTs closely spaced pulse pairs ($\sim$ 5ms interpulse intervals) are separated by longer intervals (interdoublet intervals) [31]. In Fig. 1.3

The difference between CFTs, VFTs and DFTs is visually represented through and example taken from [70].

It has been shown that VFTs and DFTs may postpone the onset of muscle fatigue and are more efficient to generate force in fresh and fatigued muscles as compared to CFTs [71, 27, 72, 73, 66]. Doublets have been shown to be preferable than single pulses, triplets or more both in terms of induced force and muscle fatigue [32].
DFT and VFT patterns are based on the nonlinear force summation [32] and on the catchlike muscle property [33]. These patterns have been shown to limit fatigue due to increased calcium release from the sarcoplasmic reticulum and increased stiffness [71, 74].
The catchlike property of the muscles is expressed as the largest amount of force generated per pulse demonstrated when a small number of pulses were delivered at a high frequency (short interpulse interval) at the onset of a lower frequency train, suggesting that the muscle fibers are able to “catch” or “hold” tension and sustain it for the duration of the train [75]. The catchlike property is an inherent property of skeletal muscle cells and is not a function of the motor neuron, the neuromuscular junction, or increased motor recruitment [76, 77, 78, 79]. The two primary mechanisms that have been proposed to explain the force-enhancing effects of the high-frequency burst in catchlike-inducing trains are increased sarcoplasmic Ca^{2+} concentration and increased stiffness of the series elastic elements of muscle [77, 80, 81, 82].

In a study, published in PLoS ONE in 2016 [83], Cometti C. et al. compared knee extensors’ neuromuscular fatigue in response to two 30-minute stimulation patterns: CTF and DFT. The study was conducted on fifteen able bodied subjects and measurements of evoked torque were taken during isometric contractions. The results showed that for DFT the force produced during the stimulation sessions was greater with similar amount of fatigue at the end of the session with respect to CFT [83]. The main limitation of this study was that it was conducted on able bodied subjects while it is known that paralyzed and non-paralyzed muscles have markedly different responses to FES. Therefore, functional fatigue responses to different stimulation protocols need to be defined specifically for paralyzed muscle [31].

In a study published in 2020, Shuang, Q. et al. [31] compared DFT and CFT on seven adults with SCI and eight able-bodied participants. To compare fatigue responses across patterns and across paralyzed and non-paralyzed muscle, they used the same relative target force (i.e., percentage of maximal contraction force). Since in those with SCI the determination of maximal voluntary contraction (MVC) is not possible due to the loss of voluntary control, they recorded the maximal stimulated contraction (MSC). DFT resulted in similar number of contraction to fatigue (defined as a 20% decline from target force) in both populations, whereas in those with SCI, CFT resulted in a lower number of muscle contractions before the onset of fatigue, meaning that the DFT pattern slowed the progression of fatigue in those with SCI. They hypothesized that this was due to the greater calcium release induced by DFT that may offset impaired calcium release resulting from fatigue [31].

A limitation of this study is the fact that the stimulation protocols were compared during repetitive isometric contractions. It would be of interest to further investigate these stimulation protocols during dynamic contractions.

Surface distributed sequential stimulation

FES is usually delivered to one muscle group via a pair of stimulation electrodes, where all recruited motor units are activated simultaneously [34]. Since one reason for rapid muscular fatigue is the activation of only a subset of motor units of the corresponding muscle [35, 36], multi-electrode setups have been developed, which allow stimulation patterns to target different motor units, showing some advantages in reducing muscle fatigue [37, 5, 38, 39, 40, 41]. With these configurations, it is possible to activate different motor units separately.

Indeed, this stimulation strategy consists in sending stimulation pulses, one after another, to every single electrode sequentially, resulting in a fused response from the low frequency unfused responses of individual electrodes. Such sequentially applied stimulation is referred to spatially distributed sequential stimulation (SDSS) [40]. The use of spatially distributed sequential stimulation (SDSS) has been shown to be effective in power generation and fatigue reduction [84, 39, 85]. Power is strongly related to the number of motor units recruited and since with SDSS the electrical field can be varied, more motor units will be activated, thus more power can be generated [86]. Whether this increase in motor units comes from the larger surface area covered with SDSS, or through the deeper stimulation by the small electrodes remains unclear [87, 88, 41]. Indeed, with SDSS the same amount of current is applied to a smaller surface area than during single electrode stimulation (SES), which generates a higher current density, and it is assumed that the resulting electrical field reaches deeper regions. The main possible drawback is that in a functional task, the resistance is constantly changing due to muscle bulk shift and skin movement and it can happen that non-targeted nerves are stimulated. Using SDSS means adding a temporal shift between the pulses that decreases the stimulation frequency for each electrode, while maintaining the same overall stimulation frequency. The lower stimulation frequency applied to each electrode allows for a lower ATP cost for each contraction and is more efficient in binding cross-bridges [8]. There are several studies that demonstrate that SDSS increases fatigue resistance significantly while maintaining or even increasing power output compared to conventional electrical stimulation [86, 89, 90, 40].

In 2009 Popović, L,Z. and Maleşević, N. [39] carried out a study on six subjects with complete SCI, stimulating the quadriceps and measuring the isometric ankle torque in two different electrode setups: SES and SDSS with four small electrodes as cathodes, positioned proximally. The evaluation parameters were the maximal torque and time interval during which torque declined from 100% to 70% of maximal value. For the same initial torque values, in the SDSS configuration large torques were maintained for longer time. The average fatigue interval prolongation was 153,18%. The stimulation frequency in the SES protocol was 40 Hz, while in the SDSS each electrode received stimulation at 16 Hz, so that the overall frequency of stimulation of the quadriceps in the SDSS protocol is 64 Hz. The value of 16 Hz was chosen as minimal frequency that produced a smooth force in every subject. As the results were obtained during an isometric contraction, it can be difficult to predict the behavior during a dynamical task such as FES-cycling.

A case study conducted by Nguyen et al. and published in 2011 in Artificial Organs [40] compared the isometric ankle torque generated through SES and SDSS of the triceps surae of a subject with complete SCI (AIS A). The total area covered by the two electrodes configuration was the same and the protocol consisted in the delivery of a two-minute fatiguing stimulation. SDSS resulted in clearly less fatigue than SES as evidenced by a lower rate of torque decline during the first quarter of stimulation and a higher torque produced at the end of stimulation. On the other hand, more fluctuations in the torque value occurred during SDSS despite constant current amplitude being set for all four electrodes. The results are promising but further investigation, especially with a substantial number of participants, are needed. One other limitation of the study is that it does not analyze a functional movement.

In 2019 Laubacher et al. published a case-series study [8] in which vastus lateralis and vastus medialis muscles of four participants with complete SCI (AIS A) were stimulated with SES and SDSS electrode setups on both legs for six minutes. The protocol involved a dynamic isokinetic knee extension task simulating the knee movement during recumbent cycling. Torque was measured during knee extension by a dynamometer at an angular velocity of 110 deg/s. Mean power of the left and right sides was higher with SDSS for all four participants for all extensions, and for the initial phase, while fatigue resistance was better with SDSS for three out of four participants. The Authors suggested that these positive results should encourage the development of more sophisticated electrode setups for use in gross motor movements, such as leg cycling. Moreover, they stressed the importance of investigating long-term training protocols and comparing SDSS and SES in SCI participants with well-trained muscles.

The most recent study about SDSS has been published by Schmoll et al. [43] in January 2021 in the Journal of NeuroEngineering and Rehabilitation. The aim of the study was to assess fatigue induced by FES of the quadriceps muscle during a dynamical knee extension protocol. Three subjects with SCI participated in the study. They were required to participate on a regular FES-based training regime of the quadriceps muscles for at least 4 months in order to allow for grater forces, as needed for functional tasks such as FES-cycling, and to minimize a potential training effect induced by the measurements, increasing the reproducibility. Four different distributed electrode configurations were compared to the conventional setup, which consist of only two electrodes placed proximally and distally on the quadriceps. The electrodes positioning in configuration POS1 of Fig. 1.4 was adapted from Maleşević et al. [39], while the configuration POS2 of Fig. 1.4 was adapted from Laubacher et al. [8]. POS3 and POS4 were targeting the motor points of vastus medialis, vastus lateralis and rectus femoris: in POS3 of Fig. 1.4 three single electrodes were used, one for each motor point, while in POS4 Fig. 1.4 four smaller electrodes were placed near each motor point. All the configurations had a common anode. POS1, POS2, POS4 implemented distributed stimulation by using anti-fatigue-units (AFU, Model: 3F-AFU-10, 3F-Fit Fabricando Faber, Belgrade, Serbia). Fig. 1.4 Shows a representation of the different configurations.

Using POS1 the Authors observed mostly unfused contractions and only sometimes strong fused contractions. Due to these problems, they were not able to obtain reliable tetanic contractions and decided to exclude POS1 from the analysis. For all the other tested configurations, the results of this study were not able to verify significant differences in the fatigue resistance compared to conventional stimulation. This finding is rather surprising as literature suggested clear benefits in the use of distributed stimulation. One possible reason for this discrepancy could be that in the precedent study conducted in subjects with SCI by Laubacher et al. [8] the dynamic fatigue-testing was performed at rather low power values. The initial power-values of [8] were in the range of 0.8W to 3.3W, which are noticeable lower than the values used in [43] (range 11,2W-23,2W), because the participants in [8] were untrained. Shmoll et al. [43] hypothesize that another factor could be the higher stimulation amplitude used in their study as required by the higher initial torque levels. They delivered 2-3 times the current per pulse as compared to Laubacher et al. [8], and they suggest that it is reasonable to assume that higher stimulation amplitude cause a certain degree of spillover and recruit additional motor-units indented to be stimulated by a neighboring electrode. Due to the loss of intra-muscular selectivity, individual muscle-parts will thus successively receive a higher stimulation frequency when increasing the stimulation amplitude. Therefore the beneficial effects of distributed stimulation regarding fatigue-resistance are less pronounced at higher stimulation amplitude.

Shmoll et al. [43] concluded stressing the fact that, although methods for improved fatigue-resistance generally support their claims with statistically significant results, it is important to acknowledge that the overall fatigue-resistance during FES is still very low, compared to voluntary contractions. In order to demonstrate a meaningful impact, it is necessary to validate potential improvements in more practical settings, i.e. at higher forces and with a higher number of contractions.

1.5 The CYBATHLON championship

The CYBATHLON is a unique championship organized by ETH Zurich in which people with physical disabilities compete against each other to complete everyday tasks using state-of-the-art technical assistance systems. The competition includes six disciplines:

- Brain-Computer Interface race (BCI)
- Functional Electrical Stimulation bike race (FES)
- Powered arm prosthesis race (ARM)
- Powered leg prosthesis race (LEG)
- Powered exoskeleton race (EXO)
- Powered wheelchair race (WHL)

The tasks included in the disciplines are typical challenges and situations that people with physical disabilities encounter in their everyday life. On the 13th of November 2020, the CYBATHLON 2020 Global Edition took place in a remote modality, due to the Covid-19 pandemic. The 51 involved teams coming from 20 different countries participated from their hometowns and recorded their performance during a live-stream connection with the organizers.

Beyond the competition, the CYBATHLON aims to serve as a platform to drive forward research on assistive devices for everyday use, and to promote dialogue between technology developers, disabled people and the general public. [42].

1.5.1 the FES-bike race

The FES-bike race was included as a discipline in the CYBATHLON competition with the intent to promote the development of FES-cycling systems which can be used by people with SCI in everyday life as a recreational outdoor activity, promoting the physical benefits induced by FES as well as the physiological benefits typical of sport activities. The pilots of the FES-bike race are people with a complete loss of motor and sensory function in the lower limbs (ASIA impairment scale score of A - www.sci-info-pages.com/levels.html). They ride a passive cycling device, that can be commercially available or custom-made. Surface and implanted stimulation technologies are allowed. During the FES-bike race the pilots should be able to cover a distance of 1200 m within a time limit of 8 minutes. During the race the stimulation intensity can be adjusted directly by the pilot or using a closed-loop control system.

1.6 Objectives

This master thesis work had two main goals:

- to optimize the prototype of FES-bike for paraplegics, to organize and supervise the training sessions of the pilot and to determine the optimal stimulation parameters for the participation in the CYBATHLON 2020 Global Edition (www.cybathlon.ethz.ch).

- to design a case study based on the experience of the CYBATHLON, with the aim to compare different stimulation strategies (constant frequency, DFTs, SDSS) in terms of FES-induced muscular fatigue.

  Up to date, limited evidence is available concerning the direct investigation of the delay of muscle fatigue during FES-cycling [91, 68, 56, 5, 92] in persons with

SCI. Nevertheless in the context of FES-cycling it would be of great relevance to determine an effective means to reduce rapid fatigue, since it would allow for people with SCI to pedal outdoor autonomously and for a sufficient amount of time to gain all the benefits listed in 1.3 Up to date no previous study can be found that compares the most promising fatigue reducing stimulation strategies (such as DFTs and SDSS) directly in a cycling task, therefore the case study developed here aims at overcoming this gap of knowledge.

1.6.1 Structure of this work

This work is organized as follows:

- Materials and methods chapter: the instrumented trike used to participate in the FES-bike race and to carry out the acquisitions for the case study is described in detail, together with the physical characteristic of the pilot. The preparation and training sessions towards the CYBATHLON competition are documented. The testing protocol for the experimental study and the statistical analysis conducted on the outcome measures are reported.
- Results chapter: the strategy adopted in the day of the FES-bike race together with the performance obtained are described here, followed by the analysis of the results of the case study.
- Discussion chapter: it comprises the conclusions of the study and the future developments.

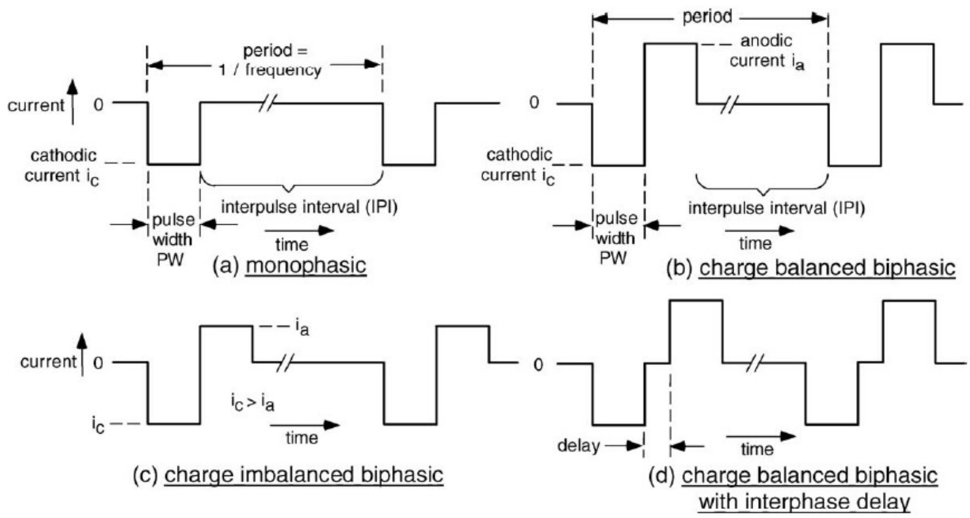

Figure 1.1: *Common pulse types and parameters, from [30]*

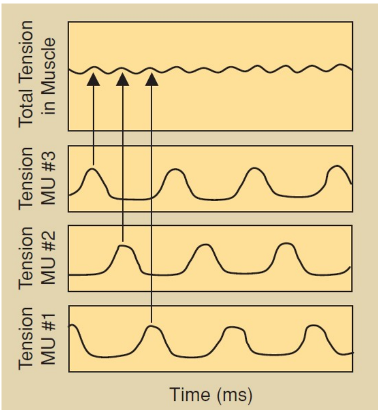

Figure 1.2: *Example of summation of motor units tension due to asynchronous recruitment in skeletal muscles, from [22]*

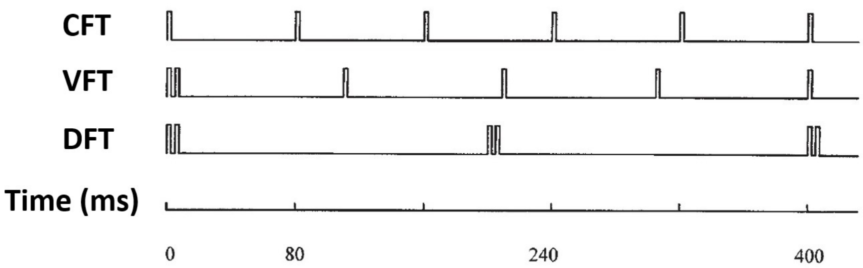

Figure 1.3: *Visual representation of different pulse trains: CFTs, VFTs and DFTs, from [70]*

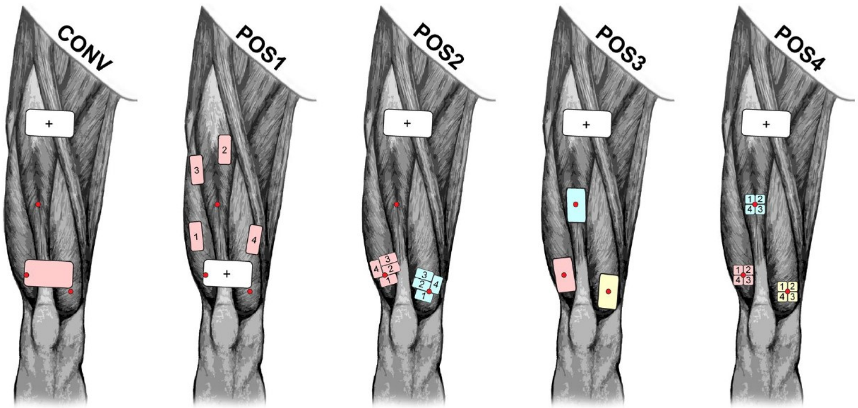

Figure 1.4: *A graphical representation of electrode placement for the different setups tested in [43], All the configurations had a common anode (white "+" electrode), the motor-points used for orientation of the electrode configuration are displayed with red-circles*

Chapter 2

Materials and methods

This chapter describes:

- The instrumented trike together with the embedded control system used for participating in the FES-bike race of CYBATHLON 2020 and for the development of the case study.
  Regarding this, the thesis work started from an already developed setup, then modified to optimize the efficacy of the stimulation.

- The identification of the stimulation strategy to pedal on the trike

- The preparation towards the FES-bike race

- The experimental protocol implemented for the case study

Figure 2.1: *The FES-bike prototype used to participate to CYBATHLON 2020 by the POLIMIRehaMove team*

2.1 Experimental setup

2.1.1 Instrumented tricycle

The trike used in this study is a commercial recumbent tricycle (ICE VTX™ 2017 - www.icetrikes.com) which has been adapted for use by paraplegic cyclists, in conjunction with FES of the paralyzed muscles of the lower limbs. The trike is completely passive and its main mechanical specifications are listed in Tab. 2.1. Fig. 2.2 displays the original commercial trike, while in Fig. 2.1 all the integration made are highlighted.

The trike has been instrumented with a magnetic encoder (AksIM™ off-axis rotary absolute encoder - www.rls.si/aksim-off-axis-rotary-absolute-encoder), which has an accuracy of more than ±0.1°and is used to acquire the angular position of the crank with a frequency of 200 Hz and a resolution of 20 bits. Crank speed can be obtained by differentiation of the angle measurements.

The pedals of the trike have been replaced with two ankle-foot orthosis (AFOs) from BerkelBike™ (www.berkelbike.com). The AFOs have an adjustable calf support, that

Figure 2.2: *ICE VTX recumbent trike*

Parameter	**Value**
Overall width	750 mm
Overall length	2030-2290 mm
Seat height	150 mm
Seat angle adjustment	23-32 °
Turning circle	7.4 m
Rider weight limit	104 kg
Overall weight of the trike	$\sim$ 13.8 kg
Rider size (X-seam)	940-1219 mm
Track width	700 mm
Ground clearance (ride height adjusted)	65mm
Wheel base	1220-1250 mm

Table 2.1: *Trike features*

has been fixed properly to ensure that hip, ankle and knee are aligned in the sagittal plane during cycling. The AFOs also makes it possible to keep the ankle angle at 90°.

2.1.2 Stimulators

For the integration of FES, two commercially available stimulators, RehaMove3™ (Hasomed,GmbH, Germany -www.hasomed.de/products/rehamove), are used. The stimulators are positioned under the seat of the trike in two 3D-printed housings. In Fig. 2.3 a picture of the stimulator is reported. Each stimulator is endowed with four channels, making it possible to deliver stimulation to four different muscle groups. In this set-up the muscle groups stimulated are quadriceps, gluteal muscles, hamstrings and gastrocnemius.The stimulators are current controlled and the provided stimuli are rectangular biphasic pulses of current, completely balanced in terms of charge and characterized by an amplitude up to 150 mA with a resolution of 0.5 mA and a pulse width up to 4000 µs with a resolution of 1 µs. The stimulators are controlled via USB and are endowed with a Matlab/simulink library together with a pre-compiled library for several compiler (e.g. GCC). In Tab. 2.2 additional characteristics of the stimulators are listed.

Power source(s)	AC and/or storage battery
Communications	USB
Number of channels	4
Current output	0-150 mA in 0.5 mA steps °
Waveform	Adjustable (16 characteristic points)
Pulse Width	10-4000 µs in 1 µs steps
Stimulation frequency	1-500 Hz
Medical device	IIa

Table 2.2: *Stimulators features*

Figure 2.3: *RehaMove3™ stimulator from Hasomed GmbH*

2.1.3 Smart trainer

The evaluation of the performances during the FES-bike race has been done using the KICKR 4.0 sensorized smart trainer from Wahoo Fitness™ - www.wahoofitness.com. In the weeks before the race, all the teams participating in the race received their KICKR from Zurich and mounted it in place of the back or front wheel. The smart trainer can be connected via Bluetooth® to a smartphone or tablet, on which the Whaoo fitness App should be installed. From the App it is possible to start and stop a workout session. During the workout session, the App displays in real time the distance covered, the linear speed, the cadence and the time elapsed (in Fig. 2.10 it is shown a screenshot of the App during a workout). After the workout these parameters can be saved to keep track of the training session. From the App it is also possible to set the resistance of the flywheel of the smart trainer (that should have been fixed at 5% for the race).

Figure 2.4: *The smart trainer KICKR from Wahoo Fitness™*

Part Number	WFBKTR120
Connectivity	ANT+ FEC, Bluetooth
Resistance Type	Electromagnetic
Flywheel Weight	7.3 kg
Maximum Power Output	2200 W
Accuracy	+/- 1%

Table 2.3: *Specifications of the smart trainer KICKR from Wahoo Fitness™*

2.1.4 User interface

The system is equipped with a display (Kuman 3.5 inches touch screen) that shows to the user the real-time value of the stimulation parameters together with some interesting performance variables:

- Time elapsed from the beginning of the stimulation (expressed in minutes)
- Cadence (in rpm)
- Linear velocity (in km/h)
- Pulse width of the stimulation (in µs)
- Frequency of stimulation (in Hz)
- Current intensities on the four muscle groups (in mA)

On the left side of the display three LEDs give additional information on the system status:

- Green LED turned ON means that the system is successfully turned ON
- Blue LED turned ON means that a program is currently running
- Red LED turned ON means that the two stimulators are turned ON, the stimulation cables are correctly connected and the electrodes are placed properly

The display and the LEDs are controlled through an Arduino Mega 2560. Arduino, dispaly and LEDs are placed in a custom-made housing that is attached on the tricycle frame, in front of the pilot.

The pilot has the possibility to change some stimulation parameters, using four push-buttons. Two of them are placed on the sides of the handlebar, the other two are attached to a small box integrated in a belt that should be fasten on the pilot abdomen. The box also includes the emergency button, that can be pushed, if necessary, to shut down instantaneously the entire system. To make it clearly visible, it is endowed with an embedded red LED.

2.1.5 Embedded control system

The core of the embedded control system (ECS) is a BeagleBone Black (BBB) from BeagleBoard™ (www.beagleboard.org), based on a AM335x 1GHz ARM® Cortex-A8 processor. In order to assure the portability of the system, the BeagleBone Black, together with a custom-made printed circuit board (PCB) is enclosed in a gray box that is opportunely attached on the backside of the seat. The box is equipped with a small fan (Easycargo™ EDL3007s05) that constitutes the cooling system, necessary to avoid a possible increase in the temperature due to the BeagleBone Black.

Debian GNU/Linux is installed on an SD card, inserted in the BeagleBone Black. The programs that control the stimulation can be saved and run on the BBB using MATLAB/Simulink® Real-time toolbox in external mode. The BeagelBone Black can communicate to a laptop via USB. This connection is fundamental to program the BBB, but once the procedure is concluded, it is possible to disconnect the laptop from the BBB that would run a pre-loaded program autonomously.

During the execution of a stimulation program, the BeagleBone Black reads the value of the crank angle from the encoder, and based on this value, it stimulates the proper muscle groups. At the same time, the crank cadence and the linear velocity are computed and are updated on the LCD, together with the stimulation parameters. Using the push-buttons the user can start and stop the stimulation and increase or decrease some of the parameters.

Encoder and BeagleBone Black exchange information using SPI protocol, while the communication between the BBB and the Arduino Mega (that refreshes the LCD and controls the LEDs) is based on UART. The stimulators are connected via USB to the BBB, through a four port Hub USB.

The custom-made printed circuit board (PCB) is placed above the BeagleBone Black, inside the hardware box. It is depicted in Fig. 2.5 and includes the debouncing circuit for the four push-buttons, consisting of a shmitt-trigger (model CD74HCT14 from Texas Instrument™), four 0.1 µF capacitors and four 1 kΩresistors. Moreover it comprises the common tracks of ground and 5V, shared between the system components.

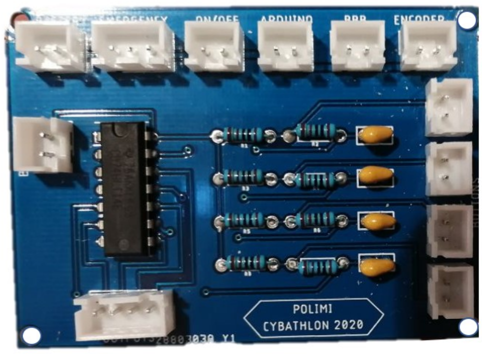

Figure 2.5: *Custom-made printed circuit board encompassing the debouncing circuit*

The power supply source of the system is a powerbank (from Anker™, model AK-A1263011) that can be connected via USB cable to the PCB. The power supply line reaches first the emergency button and then the BeagleBone Black, the Arduino Mega and the encoder. Whenever a potentially dangerous situation occurs, switching the emergency button would shut down instantaneously the system. The LCD and the LEDs receive power directly from the Arduino Mega, while the stimulators are equipped with their own internal rechargeable battery and don't need any external power supply. To hold the powerbank in place, a 3D printed housing has been placed on the back of the seat, just above the hardware box.

To reach the electronic components attached in different areas of the trike, long cables have been used, and this caused a not negligible drop of voltage. To guarantee that the power supply provided to all the components lies always in between the specified ranges, an adjustable step-up component (XL6009 DC-DC) has been added inside the hardware box, placed between the emergency button and the BeagleBone Black.

In Fig. 2.9 it is possible to see a simplified representation of all the components of the control system of the trike.

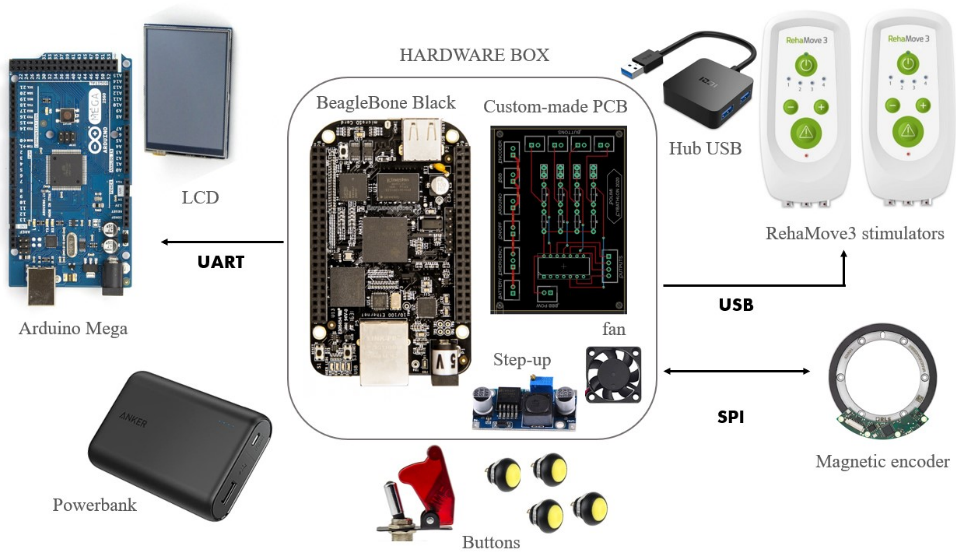

Figure 2.6: *A schematic diagram of the embedded control system*

2.2 Pilot

The pilot is 39 years old, 175 cm tall and weighs 70 kg. He is paraplegic (lesion level T5-T6) due to a bike accident occurred in March 2019 and he has an ASIA impairment scale score of A (complete loss of motor and sensory function -www.sci-info-pages.com/levels.html).

2.3 Stimulation strategy

The execution of a correct cycling movement on the trike required the stimulation of four muscles for each leg: quadriceps, gluteal muscles, hamstrings and gastrocnemius. Some initial attempts were made to accomplish a complete pedalling task with only quadriceps and hamstrings, but it was impossible because the action of gluteal muscles resulted essential to overcome the dead point. In the recumbent position, the dead point corresponds to the position of the pedals in which one knee is almost completely extended and the other is still flexing. In this position the quadriceps of the extended leg has stopped contracting whilst the quadriceps of the flexed leg is not contracted yet. Thus the hip flexion activity of the gluteal muscles results necessary to continue the movement. The contribution of the gastrocnemius is not strictly vital, yet it enhances the smoothness of the pedalling.

The precise activation angles of the four muscles were set starting from a previous study carried out on healthy subjects who were asked to pedal on the trike while measures of the EMG activities of the same muscle groups were taken. The resulting stimulation angular ranges were optimized on the pilot through a trial and error procedure. In particular, stimulating each muscle at a time, it was possible to identify the angle ranges in which every muscle is functional to the movement. In Fig. 2.7 the activation ranges are represented with different colours as measured by the magnetic encoder. The zero angle for the encoder has been arbitrarily set when the right foot is higher in correspondence of the vertical axis. The dead point is located at 90°. In Tab. 2.4 the start and stop angle for each muscle group are listed.

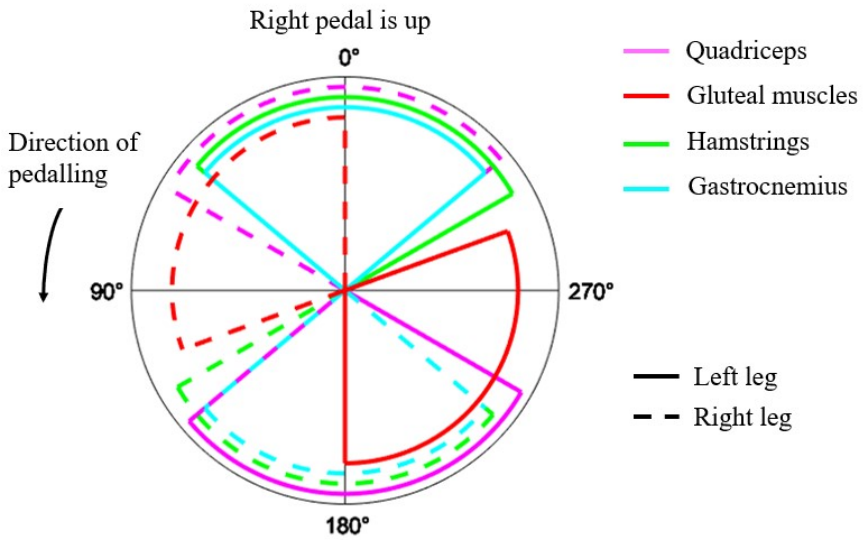

Figure 2.7: *Activation angles of the different muscle groups stimulated. The zero angle corresponds to the crank position in which the right pedal is up on the vertical axis*

Each one of the two stimulators was used to activate the muscles of one leg, exploiting one channel for each muscle group (as listed in Tab. 2.5). The waveform used was rectangular biphasic balanced in charge.

Muscles	**Start angle**	**Stop angle**
Left quadriceps	130°	240°
Left gluteus	180°	290°
Left hamstrings	300°	50°
Left gastrocnemius	310°	50°
Right quadriceps	310°	60°
Right gluteus	360°	110°
Right hamstrings	120°	230°
Right gastrocnemius	130°	230°

Table 2.4: *Activation ranges for each of the eight stimulated muscles*

Muscles	**Channel**	**Colour**
Quadriceps	Channel 1	Red
Gluteal muscles	Channel 2	Blue
Hamstrings	Channel 3	Black
Gastrocnemius	Channel 4	White

Table 2.5: *Stimulator channels for each muscle group. The colour of the cables for each channels is also reported*

Two electrodes (PALS® reusable electrode from Axelgaard Manufacturing.Co.) were placed on each muscle group. The size of the electrodes used is specified in Tab. 2.6 whilst in Fig. 2.8 the positioning of the electrodes is depicted.

Muscles	**Proximal electrode**	**Distal electrode**
Quadriceps	5cm x 13cm	5cm x 9cm
Gluteal muscles	5cm x 9cm	5cm x 9cm
Hamstrings	5cm x 13cm	5cm x 9cm
Gastrocnemius	5cm x 9cm	5cm x 9cm

Table 2.6: *Electrodes dimension for each muscle group*

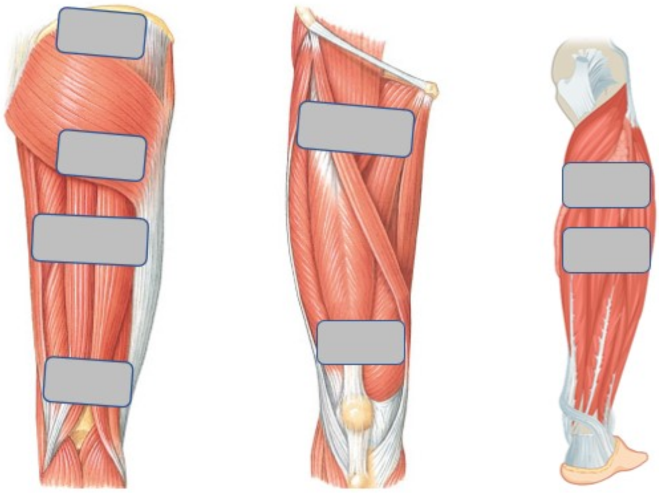

Figure 2.8: *Schematic representation of the electrode placement over quadriceps, gluteal muscles, hamstrings and gastrocnemius*

2.4 Preparation towards CYBATHLON 2020

On September 29th 2019, the Ethical Committee of Politecnico di Milano approved the research study involving the participation of CYBATHLON 2020. A medical insurance was stipulated in order to cover any possible risk related to FES-cycling training. The pilot gave his informed consent to participate in the study.

2.4.1 Rules of the race

Every team had three attempts (or races) to try to make their best performance. The aim of the races was to cover the distance of 1200m as quickly as possible or, in case none of the pilots reached the finish line, to cover as much distance as possible within the race time limit of eight minutes.
The distance had been increased compared to the CYBATHLON 2016, when it was 750 m, thus, an improved performance was expected from the participants. The race must be carried out with the resistence of the KICKR set to 5%. Each race consisted of a warm-up period and the actual race period. The warm-up period substituted a physical ramp or initial push by a support person that is usually required to overcome the system-inherent moment of inertia and static friction when starting from a complete standstill.

During the warm-up period, the smart trainer was accelerated to a maximum speed of 10km/h. The movement of the legs during the warm-up period could be accomplished by the following means:

- The pilot's arms
- FES to the pilot's legs
- With the help of a support person that moves the pilot's legs
- A combination of these three options.

At the end of the warm-up period the race started automatically. Acoustic and visual signals marked the start of the warm-up period as well as the start and end of the race period. Approximately forty-five minutes elapsed between each try. A live stream connection with Zurich had to be maintained during each of the three attempts, using Discord instant messaging/VoIP application. Moreover, one external person had to be present on the site of the race in the role of the time-keeper. It was the time-keeper that had to start the workout from the Wahoo application as soon as the 30 seconds warm up phase ended and the race phase started.
At the end of each eight minutes races, the time-keeper had to be ready to stop the workout, save the data of the performance and send it in .fit format to the official organizers. The time-keeper was also provided with a computer, with the software T.A.C.S. (the official event-management system of CYBATHLON) already installed. The interface of T.A.C.S. allowed the time-keeper to signalize the servers in Zurich about important events occurring during the race phase:

- When the pilot hit one of the six 200m segments in which the 1200m race track was divided

- If the pilot had received a warning because of extensive use or any other misuse of hand or arm (during the race, hands or arms are allowed to be used to push on the legs to overcome pedalling dead points, but not to support on-going propulsion).

- Race abortion because the pilot was stuck, or had received three warnings

In front of the pilot a large screen was synchronized with T.A.C.S showing the timing, the distance covered and the eventual warnings. While the view of the Wahoo App was mirrored in another smaller screen. In Fig. 2.9 a picture of the day of the race show the point of view of the pilot, with the two screens in front of him and the time-keeper station on his left side. While in Fig. 2.10 it is possible to see the interfaces of T.A.C.S. and Wahoo App that were managed by the time-keeper.

Figure 2.9: *a. A picture of the day of the race where it is possible to see the time-keeper on the left side with the computer running T.A.C.S. and the smartphone running the Wahoo app. b. In front of the pilot the big screen is synchronized with T.A.C.S. while the small screen is mirroring the Wahoo app c. Scheme of the set-up provided by the organizers.*

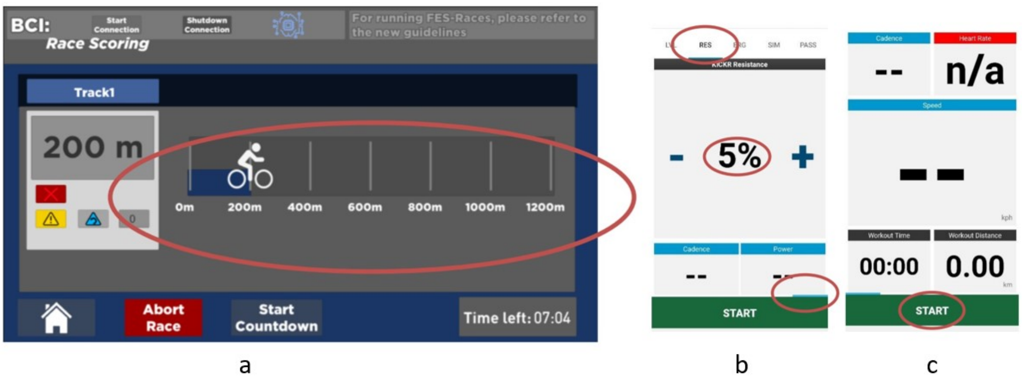

Figure 2.10: *a. The window of T.A.C.S. that the time-keeper was seeing during the race. b. The window of Wahoo App from which it is possible to start the workout. C. The window of Wahoo App from which the value of the resistance can be set*

2.4.2 Training sessions

The training of the pilot on the trike started on the 29th of September 2020. Before that date, only training sessions on a stationary cycle ergometer were performed.

The pilot was trained on the trike twice a week almost every week from the 29th of September to the 11th of November (the day in which the performances for the race were recorded) for a total of ten training sessions. The first sessions were spent optimizing the stimulation angles, and the values of current amplitude for each muscle, thanks to a calibration program that made it possible to stimulate one muscle group per time. Subsequently, some attempts to compare the effects of different constant frequencies trains (30 Hz, 40 Hz and 50 Hz) and doublet frequency trains ($\sim$ 10 ms interpulse interval and 50 ms interdoublets interval) were made. The absence of a torque sensor on the trike, made it difficult to discern which one of the stimulation patterns was producing the higher power output. Nevertheless, with 50 Hz the smoothness of pedalling was visibly compromised so it was excluded. Short one minute acquisitions were recorded at 30 Hz, 40 Hz and DFTs in different days, randomizing the order of the tries, but no recognisable difference in the performance was noted.
The final decision was to exclude DFTs as less flexible, and to let the pilot switch the stimulation frequency from 30 Hz to 40 Hz with one of the push button in the belt, during the race.

The remaining training session were organized to resemble the day of the race. Three eight minutes tries were performed, attempting to cover the greater distance. Fifteen minutes of rest, instead of forty-five, were included between each try, due to time limitations. Each of the tries was organized as follow.
The pilot could control the moment in which the stimulation starts and stops pushing the right button of this belt. Before starting the stimulation, the proper front and back gears were set. To overcome the initial inertia, one member of the team helped the pilot pedaling at about 40 rpm.
During the stimulation, the pilot was given the possibility to:

- Change the gears
- Increment by 10 mA the current amplitude up to 130 mA, pushing the button in the left handlebar
- Decrement by 10 mA the current amplitude, pushing the button in the right habdlebar
- Increment the stimulation frequency from 30 Hz to 40 Hz with the left button on his belt

The only stimulation parameter that the pilot couldn't control was the pulse width, that was set at 400 µs at the beginning of the try and was automatically increased to 500 µs after 4 minutes of stimulation.

Before the day of the race, the program that had to be run in the competition was saved on the BeagleBone Black, and an auto-run algorithm was implemented, so that once the system was turned on and the stimulators were connected to the hardware box, the program should have started automatically.

2.5 Experimental study

The study conducted in the months after the race had the main objective to compare different stimulation strategies in terms of muscle fatigue, during a FES-cycling task. The starting point for the study was the experience in the CYBATHLON 2020 GLOBAL EDITION. The study has been developed in the form of a single case study, with only one participant, namely the pilot of the CYBATHLON competition, whose physical characteristics have been described in section 2.2.
When the study started (end of January 2021), the pilot was at his fifth month of training with electrical stimulation, with only a brief interruption during the Christmas Holidays. To perform the cycling task, the same muscle groups and the same activation ranges (indicated in Tab. 2.4 and Fig. 2.7 and optimized for the FES-bike race) have been exploited.

2.5.1 Stimulation strategies

The four stimulation strategies tested in the experimental study are:

1. Stimulation with constant frequency trains at 30 Hz
2. Stimulation with constant frequency trains at 40 Hz
3. Stimulation with doublets frequency trains (DFTs) with an interpulse interval of 5.8 ms and an interdoublets interval of 50 ms, i.e. two closely spaced impulses sent with a frequency of 20 Hz
4. Surface distributed sequential stimulation (SDSS) on the quadriceps, with a single electrode placed proximally and four smaller electrodes placed distally. The electrical pulses are sent in sequence to the small electrodes, with each small electrode active at 10 Hz, whilst the overall stimulation frequency is 40 Hz

In Fig. 2.11 a graphical representation of the pulse patterns for each stimulation strategy tested in the case study is reported.

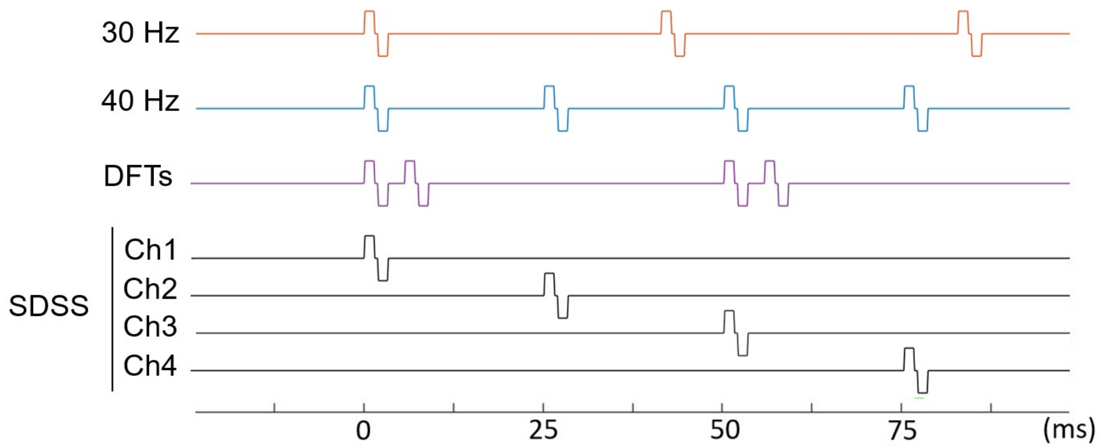

Figure 2.11: *The pulses sequence for the different stimulation strategies*

Constant frequency stimulation at 30 Hz and 40 Hz

The choice to include the two constant frequency trains stimulation patterns was influenced by [68] and by some observation made during the training period before the race. In [68], Eser et al. highlighted a 25% higher power output when using a stimulation frequency of 60 Hz compared to 30 Hz without any visible difference concerning fatigue. In the weeks before the race, some attempts were made to improve the power output with higher frequencies, but the smoothness of the pedaling was compromised when reaching 50 Hz and 60 Hz. So in the day of the race frequencies of 30 Hz and 40 Hz and no higher ones were used. Still it seemed interesting to investigate if any evident difference could be detected between performances at 30 Hz and 40 Hz. The electrode configuration used to test these strategies is the same exploited in the race (described in Fig. 2.8). The dimensions of the PALS® (Axelgaard Manufacturing.Co) reusable electrode used are reported in Tab. 2.6.

Doublet frequency trains (DFTs)

For what concerns the stimulation pattern featuring doublets, the choice to send the couples of pulses with a frequency of 20 Hz was made to allow a comparison with the constant frequency trains at 40 Hz, since the number of pulses sent over time is the same. The interpulse interval of 5,8 ms was decided as values around 5 ms are considered to be optimal to exploit the catch-like property of the muscles [93]. DFT stimulation has been carried out using an electrode configuration identical to the one used to test constant frequency stimulation at 30 Hz and 40 Hz.

Surface distributed sequential stimulation (SDSS)

The surface distributed sequential stimulation has been performed using anti-fatigue units (AFU, model 3F-AFU-10 from 3F-Fit Fabricando Faber, Belgrade, Serbia - www.3-x-f.com) that work as pulse splitters, having one input and four outputs. Two AFUs were used, one for each quadriceps. Each AFU takes as input the train of pulses at 40 Hz and distribute each pulses to only one output in a shuffling manner. Differently from the other stimulation strategies that have been applied to all the muscles indistinctly, the SDSS has been applied only on quadriceps.

Therefore the placement of the electrodes on the quadriceps was different with respect to the one adopted to test the other three strategies. In Fig. 2.13 the two distinct

Figure 2.12: *Anti-fatigue units - www.3-x-f.com. The single input pin should be connected to the stimulation cable. The stimulation pulses are split to the four electrodes connected to the output pins*

electrode configurations applied on the quadriceps for the study are illustrated. In the SDSS set-up the distal electrode has been replaced with four smaller electrodes (5 cm x 5 cm).

The decision to place the four small electrodes distally has been taken following an experimental study carried out by Laubacher et al. in 2016 [41]. In the study a comparison of proximally versus distally placed SDSS electrode configuration has been made during a dynamic knee extension task. The distal placement resulted in a moderately higher power output in the final stage, so it was suggested to be preferable.

Differently from what was done in [41], and in other studies on SDSS [8],[40], in this study the total area covered by the four electrodes of the SDSS configuration was not kept equal to the area of the single electrode used in SES configuration. To keep the same area, smaller electrodes should have been used to test SDSS. Still, this option was excluded for safety reasons: the cycling task requires strong currents that applied on smaller electrodes generate high current densities, possibly raising the risk of tissue damage. The precise positioning of each of the four small electrode used for SDSS, was established during a try and error procedure. The electrodes were activated at slow frequency, making it possible to see the muscle contraction determined by every single pulse. The electrodes were shifted until a configuration in which each one of them was eliciting the contraction of different muscle fibers was found. The sequence of activation of the electrodes was established to maximize the distance between the electrode activated by the previous pulse and the electrode activated by the next pulse.

The electrodes have been attached to a thin transparent plastic sheet, in order to improve the symmetry between the two legs and the replicability of the set-up.

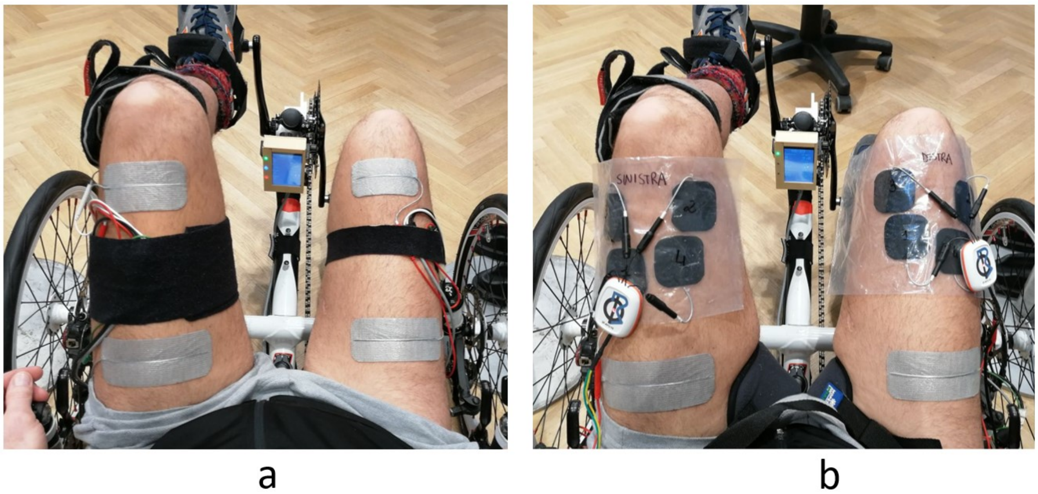

Figure 2.13: *a. Electrode placement for testing at constant stimulation (30Hz, 40Hz, DFT) b. Electrode placement for spatially distributed sequential stimulation*

2.5.2 Testing protocol

The aim of the study was to compare the four different stimulation strategies (30 Hz 40 Hz DFT and SDSS) during a cycling task.

The testing protocol has been developed with the aim to assure a fair comparison between the stimulation strategies during the FES-cycling task. In this context, the decision to maintaining a constant workrate during the acquisitions was made because it guarantees more systematic and calibrated measures [94]. If the cycling resistance is kept constant, the requirement of constant workrate can be translated into a requirement of constant cadence cycling [94].

To keep the cadence constant, it is necessary to compensate for the effect of muscle fatigue, and the consequent power output decrease. This has been obtained by increasing the current amplitude of the same amount for all the muscle groups, which resulted in the recruitment of additional nonfatigued muscle fibers [24]. The amplitude cannot be increased indefinitely, hence, a maximum in the compensation for fatigue exists, after which the power output will decrease. The duration that a subject with SCI is able to cycle at a constant power output depends, therefore, on the duration that current amplitude is submaximal [24]. If one of the strategy proves to be able to increase the duration of submaximal stimulation, it means that it could be used to postpone the onset of fatigue. The maximum value for current amplitude was selected to be 120 mA for quadriceps, gluteal muscles and hamstrings, and 115 mA for gastrocnemius. These saturation values have been considered optimal as they guarantee a high power output, and are completely safe for the pilot. The saturation current for gastrocnemius has been kept at 115 mA because the muscle group is smaller when compared to the other muscle groups stimulated.

To guarantee a constant resistance during the tests, the gears of the trike have been set as follow:

- 1^{st} gear on the front (22 teeth)
- 5^{th} gear on the back (30 teeth)

leading to a transmission ratio of 1,36 and a constant linear velocity of 6.1 km/h. The test sessions have been performed leaving the smart KICKR attached to the trike and setting the KICKR resistance to 5% through the Wahoo App.

When choosing the target value of cadence, some considerations were made: for high values of cadence (over 50 rpm) the pedalling resulted to be less smooth, almost jerky, because of the reduced inertia exerted by the flywheel of the KICKR, while for low values of cadence (under 20 rpm) each muscle group was stimulated for a too long interval of time, causing fatigue to increase too rapidly. Therefore, after some try and error procedures, 35 rpm was elected as the optimal value of cadence.

Pedalling at constant cadence required the implementation of a closed loop control system. The controller used was a discrete PI (proportional and integral) controller.

Its operating principle is expressed by the equation:

$$u(t) = K_P e(t) + \frac{K_I}{\tau} \sum e(t)\Delta t \tag{2.1}$$

The controller takes as an input the error e(t), namely the difference between the target cadence (35 rpm) and the actual value of the cadence. The output u(t), in this case, is the current intensity necessary to reach the target cadence value. The PI controller acts incrementing or decrementing the current amplitude of the four muscle groups by the same amount. The sign and magnitude of the increment is determined by the sign and magnitude of the difference between the target cadence and the actual cadence, following the eq. (2.1).
The real-time value of cadence is obtained as the first derivative of the angle, acquired at 200 Hz from the encoder. Before evaluating e(t), a low pass filter (Second order Butterworth filter with cutoff frequency of 2 Hz) is applied to the computed cadence. To estimate the output, the PI controller exploits the values of the proportional constant K_P and the integral constant K_I, that determine the speed and the stability of the response. The optimal values for K_P and K_I were tuned with a trial and error procedure which led to find:

- $K_P = 0.0025$
- $K_I = 0.0050$

The output of the PI controller was limited between 0 mA and 120 mA/ 115 mA. Setting the saturation limits to the PI required also to select an anti-windup method to discharge the integrator when saturation is reached. Back calculation method, that discharge the integrator using a feedback loop, was chosen among the method already implemented inside the PI block of Simulink®.

The testing protocol involved 12 testing sessions, in which all the four stimulation strategies were tested in a randomized order, during four different trials. At least 24 hours of rest between each testing session were required. Each of the four trial within a session was stopped one minute after reaching saturation, or after 15 minutes from

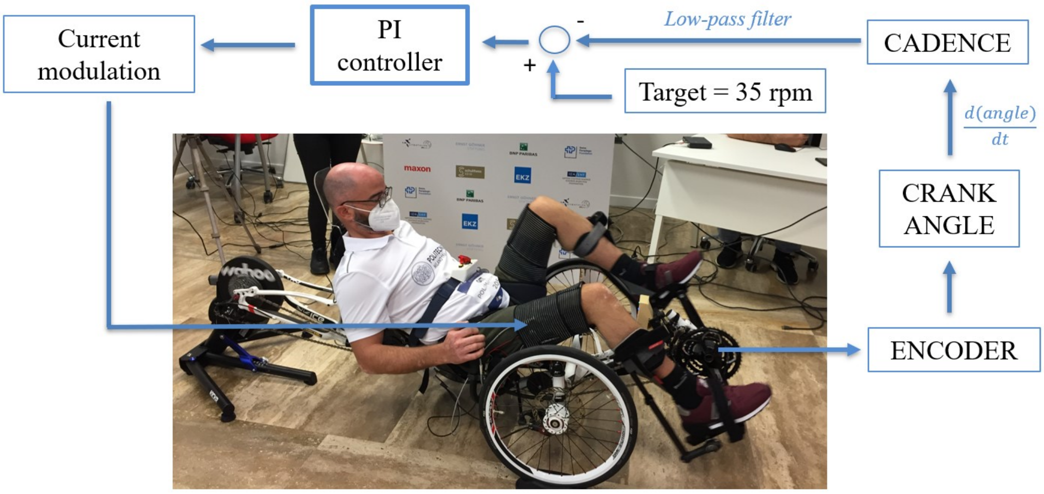

Figure 2.14: *A schematic representation of the closed loop control system implemented to obtain a constant cadence pedalling at 35 rpm*

the beginning of the stimulation. Between consecutive trials a rest period of 5 minutes was waited.

At the beginning of every test session a calibration program was run with back gear at one. The calibration program was used to stimulate the gluteal muscles to verify the correct positioning of the electrodes on those muscles. Successively the four trials were executed in a randomized order. During the execution of the four trials, the back gear was kept at 5 (22 teeth) for the first 10 test sessions and was incremented to 6 (19 teeth) in the session number 11 and to 7 (17 teeth) in the session number 12 to counteract the effect of muscle training and allow for the reaching of current saturation within the 15 minutes provided. At the beginning of each trial one person moved the legs of the pilot to reach the target cadence of 35 rpm. At that point, the pilot started the stimulation using the right button on his belt. The values of current at the beginning of the stimulation are listed in the second column of Tab. 2.7. The PI controller was activated together with the stimulation. The total current amplitudes were limited between zero and the saturation values, listed in the third column of Tab. 2.7.

The pulse width of the stimulation was kept fixed at 400 µs for all the muscles during the overall testing session. Each test session lasted about 2 hours.

Once concluded the 12 acquisitions of the experimental protocol, a test trial has been

Muscle	Initial current	Saturation current
Quadriceps	60 mA	120 mA
Gluteal muscles	60 mA	120 mA
Hamstrings	60 mA	120 mA
Gastrocnemius	55 mA	115 mA

Table 2.7: *Initial and saturation value of current amplitude for each muscle group*

made to verify whether the level of training was increased in the two months of the study. This final trial lasted 8 minutes, in which the pilot tried to reach the same target distance of 1200 m of the FES-bike race.

2.5.3 Outcome measures

The main outcome measure used to evaluate the cycling performance was the **saturation time, T**$_{sat}$, i.e. the amount of time elapsed from the beginning of the stimulation until saturation is reached.

An additional parameter estimated was the **root mean square error of the cadence** with respect to the target cadence (**RMSE**$_{cadence}$). It gives a numerical indication of the smoothness of the pedalling movement and it's calculated as explained in eq. (2.2).

$$RMSE_{cadence} = \sum_{n=1}^{N} \frac{(Cadence_{target}(n) - Cadence_{actual}(n))^2}{N} \tag{2.2}$$

Moreover the distance covered before saturation along with the distance covered in the minute after stimulation, whenever this was reached, were evaluated.

2.5.4 Statistical analysis

Considered the limited number of acquisitions (12), the statistical analysis has been performed using non-parametric tests.

Specifically, the Kruskal-Wallis test has been executed to find out whether some statistical difference in the outcome measures could be found comparing each trial with respect to the stimulation strategy adopted. Moreover, statistical differences were investigated also with respect to the temporal order in which the trial was executed. The results of the test have been considered significant for p-values smaller than 0,05.

If a signficant difference was found a post-hoc analysis with Bonferroni correction was carried out.

Chapter 3

Results

3.1 Strategy for the FES-bike race

The stimulation strategy for the FES-bike race was established on the basis of the performances observed in the training sessions and described in 2.4.2.

Regularly, during all the training sessions, the initial response of the pilot's muscles to the current was really powerful, determining an initial boost of the cadence. After the first minute, the effect of muscle fatigue became visible and there was a drop in the produced power output.

To exploit the initial peak of performance, the idea was to set a really high gear at the beginning of the race. The following best gears combination was found with a trial and error procedure:

- Gear one in the front (30 teeth)
- Gear nine in the back (13 teeth)

This strategy was tested in the last training session and it resulted to be successfully,

considering that the pilot was able to maintain a linear speed widely above 10 km/h for the whole first minute of stimulation.
After the first minute of stimulation, the muscles started to fatigue and it was necessary to decrease the back gear and increase the currents to keep pedalling. The linear speed trend during the last eight minute try before the race is reported in Fig. 3.1.

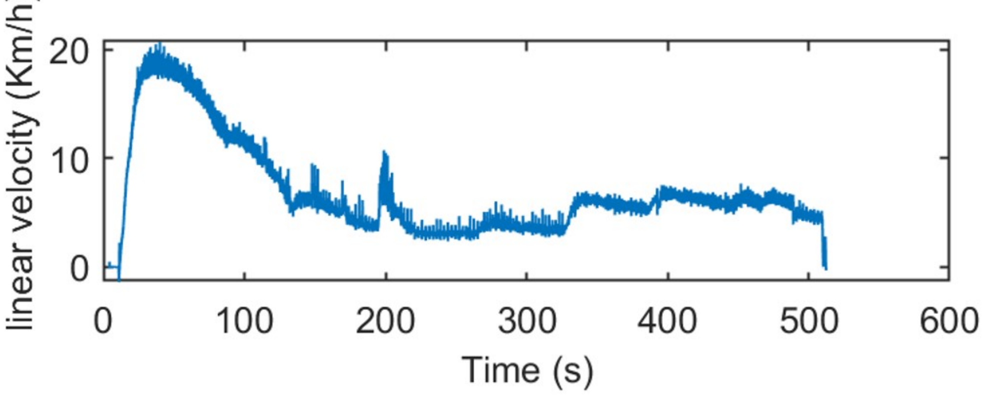

Figure 3.1: *Plot of the linear velocity achieved in the last training session before the race.*

The initial values of currents for the race were chosen to allow the pilot to start pedalling easily, even with gear nine, without going over 50 RPM cadence, where the efficiency of pedalling always had shown a decrease. The values are reported in Tab. 3.1 and were tested during the last training session.

Muscles	**Initial current intensity**
Left quadriceps	70 mA
Left gluteal muscles	70 mA
Left hamstrings	70 mA
Left gastrocnemius	65 mA
Right quadriceps	70 mA
Right gluteal muscles	70 mA
Right hamstrings	70 mA
Right gastrocnemius	65 mA

Table 3.1: *Initial values of current amplitude used in the day of the race*

Thus, in the day of the race, the initial gear was kept at one in the front and nine in the back, the initial values of currents used were the ones reported in Tab. 3.1, the initial pulse width was 400 µs and the initial value for the stimulation frequency was 30 Hz. The strategy aimed at covering the greater possible distance in the first minute, exploiting the high initial gear. After the initial boost, to limit the drop in power output, the pilot was supposed to increment manually the current amplitude by 20 mA. The current was still kept under 100 mA before minute 4 in order to preserve the muscles from exhaustion. Then at minute 4, the program was written to automatically increase the pulse width from 400 µs to 500 µs. The value of 100 mA was planned to be reached at around minute 5, as this value is particularly efficient in activating the pilot's muscles, guaranteeing an increment in the linear speed. In the last two minutes of the race, the objective was to obtain a final sprint, by means of increasing the stimulation frequency to 40 Hz and the current up to the maximum value of 130 mA.

In Tab. 3.2, it is possible to see in detail the strategy implemented the day of the race.

Minute	**Action**
Around 1.30	Increment of 10 mA in the current amplitude
Around 2.30	Increment of 10 mA in the current amplitude
4.00	Pulse width automatically increased from 400 µs to 500 µs
Around 4.30	Increment of 10 mA in the current amplitude
Between 5.00 and 5.30	Increment of 10 mA in the current amplitude
Around 6.00	Frequency increased from 30 Hz to 40 Hz
Between 6.00 and 7.00	Increment of 10 mA in the current amplitude
Between 7.00 and 8.00	Increment of 10 mA in the current amplitude, reaching the maximum value of 130 mA

Table 3.2: *Strategy for the race*

During the whole stimulation phase, the gears were supposed to be changed by the pilot to maintain the cadence between 20 RPM and 50 RPM. This range was established because it was observed that cadence values under 20 RPM were disadvantageous in terms of muscle fatigue, since each muscle was consecutevely stimulated for a long period of time. At the same time, values over 50 RPM resulted to be less efficient due to the lower resistance exerted by the flywheel of the smart trainer for those values of cadence, resulting in a less smooth pedalling. Moreover at values of cadence around 50 RPM, the force exerted by the leg was too much for the AFO to keep the legs correctly on the sagittal plane.

3.2 Performance obtained at CYBATHLON 2020

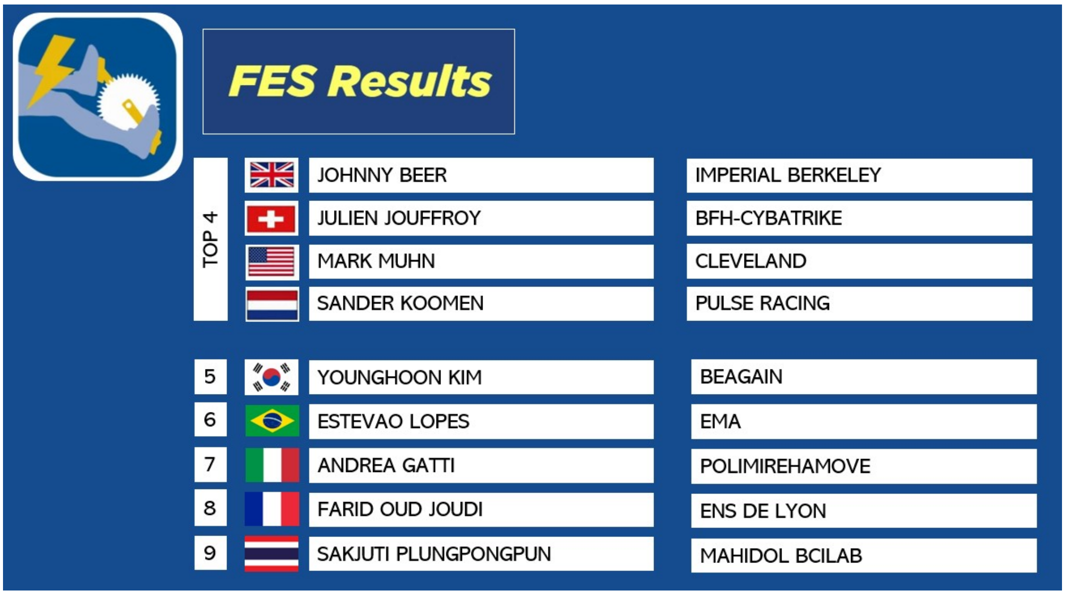

Figure 3.2: *Final classification of the FES-bike race in CYBATHLON 2020 global edition*

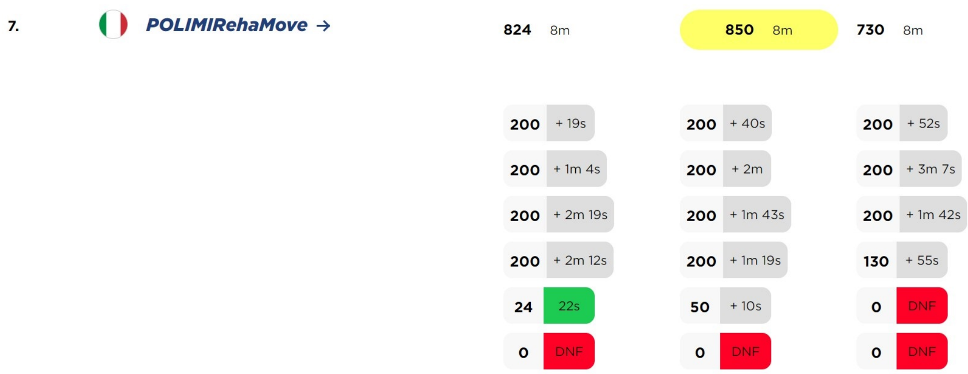

Figure 3.3: *Performance and distance covered for each attempts of the race. The time to cover every 200 m section is also reported*

Fig. 3.2 displays the final classification of the nine teams that participated in the FES-bike race of CYBATHLON 2020 GLOBAL EDITION. The PolimiRehamove team was ranked number seven. The pilots of the top three teams, as well as the pilot of EMA team were also participants in the CYBATHLON 2016. Only Mark Mhun of the Team

Cleveland used an implanted FES-device while all others used surface electrodes. In Fig. 3.3, more details of the performance of our pilot are reported.
The best attempt resulted to be the second one. The total distance covered in eight minutes was 850m, corresponding to an average linear speed of 6.4 km/h. Consistently with the implemented strategy (explained in 3.1), the initial speed was really high for all the attempts. In particular, during the first attempt, the first 200 m section, was covered in 19 s, with an average speed of 38 km/h, that was the highest value reached during the race. After this sprint, rapid fatigue of the muscles caused a drop in the linear speed. The initial sprint of the first attempt was very powerful, but fatigue increased too soon, so that the overall performance was not optimal (a total distance of 824 m was covered).
The efficiency of the stimulation in the second attempt was higher and the performance more balanced between the different segments of the trial. The initial speed was around 18 km/h. The linear velocity drop was still clearly visible during the second 200 m section. Yet, during the final four minute of the race, the increment of the stimulation parameters was effective in counteracting muscular fatigue and it was possible to slighly increase the speed and reach the best performance of 850 m. In the third and last attempt, the muscles began to show signs of exhaustion. The initial boost almost drained them, therefore the second section was covered with difficulty. During the third section the muscles recovered a bit and the pilot managed to cover 730m in 8 minutes .

3.3 Results of the experimental study

3.3.1 Acquired data

In Tab. 3.3, the order in which the four stimulation strategies (30Hz, 40Hz SDSS, DFTs) were tested over the twelve testing sessions is reported.

- Constant frequency 30 Hz was tested as first strategy 4 times, as second strategy

Session	1^{st} trial	2^{nd} trial	3^{rd} trial	4^{th} trial	gear
1	DFTs	30Hz	SDSS	40Hz	5
2	40Hz	DFTs	SDSS	30Hz	5
3	DFTs	40Hz	30Hz	SDSS	5
4	30Hz	SDSS	40Hz	DFTs	5
5	SDSS	40Hz	DFTs	30Hz	5
6	40Hz	30Hz	DFTs	SDSS	5
7	SDSS	DFTs	30Hz	40Hz	5
8	SDSS	30Hz	DFTs	40Hz	5
9*	30Hz	40Hz	DFTs	SDSS	5
10	30Hz	SDSS	DFTs	40Hz	5
11	30Hz	DFTs	40Hz	SDSS	6
12	40Hz	30Hz	SDSS	DFTs	7

1st trial
2nd trial
3rd trial
4th trial

Table 3.3: *the 12 acquisition of the testing protocol. The randomized order for each test session is listed. * For the acquisition number 9 only three muscle groups has been stimulated (quadriceps, gluteal muscles and hamstrings)*

3 times, as third strategy 2 times, and as fourth strategy 2 times.

- Constant frequency 40 Hz wasn tested as first strategy 2 times, as second strategy 3 times, as third strategy 2 times, and as fourth strategy 4 times.

- DFTs was tested as first strategy 2 times, as second strategy 3 times, as third strategy 5 times, and as fourth strategy 1 time.

- SDSS was tested as first strategy 3 times, as second strategy 2 times, as third strategy 2 times, and as fourth strategy 4 times.

The acquisition number 9 was done stimulating only three muscle groups: quadriceps, gluteal muscles and hamstrings. The gastrocnemius was not stimulated due to the presence of some red circular spots of approximately 1 mm diameter on the skin where the electrodes had been placed during the previous sessions. These small sores were probably due to spots of higher current density due to a bad electrode-skin contact. Within one week the skin was completely healed, thus in the following sessions, the stimulation of the gastrocnemius was re-introduced.

The testing sessions were performed within two months, during which the effect of training was visible, leading to an overll increment of the saturation time in all trials.

In order to keep the saturation time within 15 minutes, the acquisition number 11 was made setting the back gear to 6 (20 teeth), whilst for the acquisition number 12 the back gear was set at 7 (17 teeth).

3.3.2 Closed loop control of the cadence

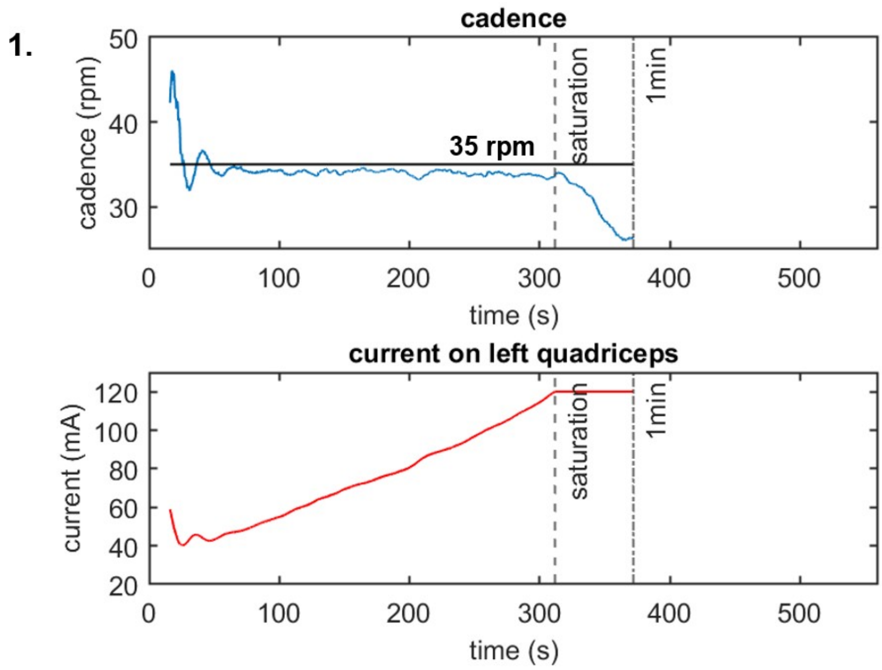

Figure 3.4: *First trial of the test session number 7 in which SDSS has been tested. The filtered cadence is plotted in blue. A black solid line specify the target cadence (35 pm). The red plot shows the action of the PI controller on the current amplitude necessary to keep the cadence constant.*

In Fig. 3.4 Fig. 3.5,Fig. 3.6 and Fig. 3.7 data from the acquisition number 7 are depicted. The first strategy tested was SDSS, followed by DFTs, 30 Hz and 40 Hz. For each trial the blue plot displays the cadence, that is maintained around the target value of 35 RPM by the PI controller. The red plot reports the value of the current amplitude for one of the stimulated muscle (namely the left quadriceps, but all muscles received the same increment of current amplitude). The controller operates to counteract the effect of muscular fatigue by increasing the current amplitude, hence recruiting additional motor fibers. The current can be increased until the maximal value of 120 mA is

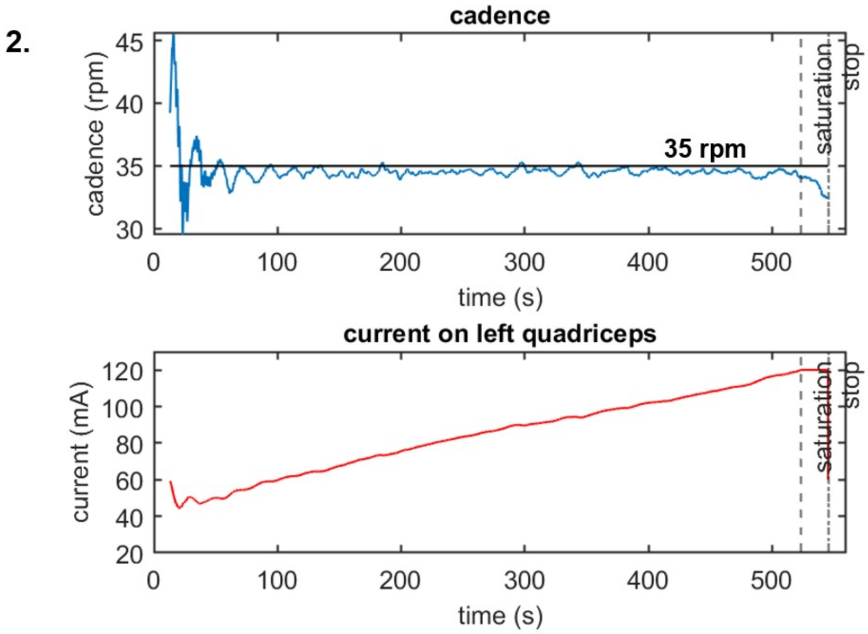

Figure 3.5: *Second trial of the test session number 7 in which DFTs has been tested. The filtered cadence is plotted in blue. A black solid line specify the target cadence (35 pm). The red plot shows the action of the PI controller on the current amplitude necessary to keep the cadence constant.*

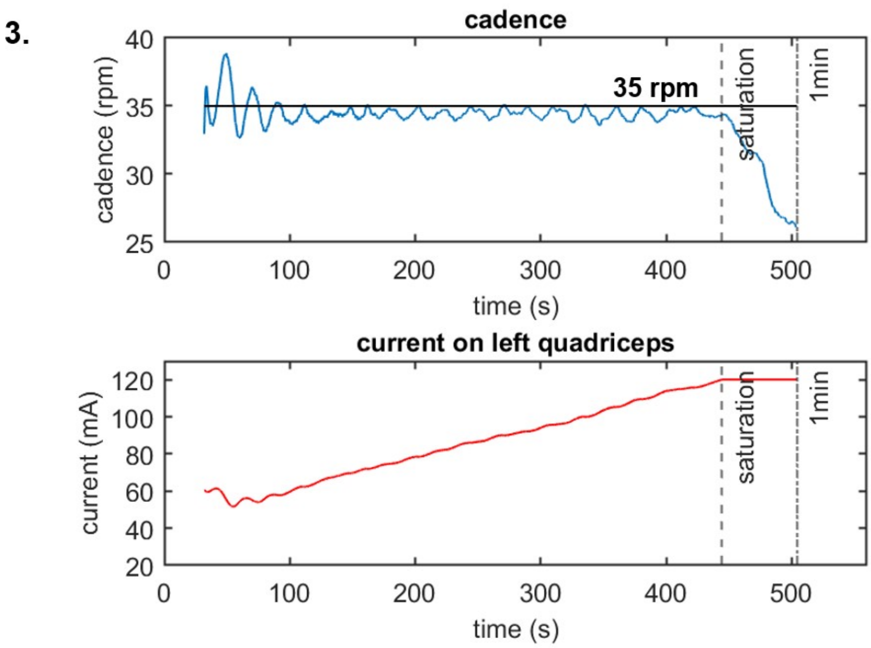

Figure 3.6: *Third trial of the test session number 7 in which stimulation at 30 Hz fixed has been tested. The filtered cadence is plotted in blue. A black solid line specify the target cadence (35 pm). The red plot shows the action of the PI controller on the current amplitude necessary to keep the cadence constant.*

4.

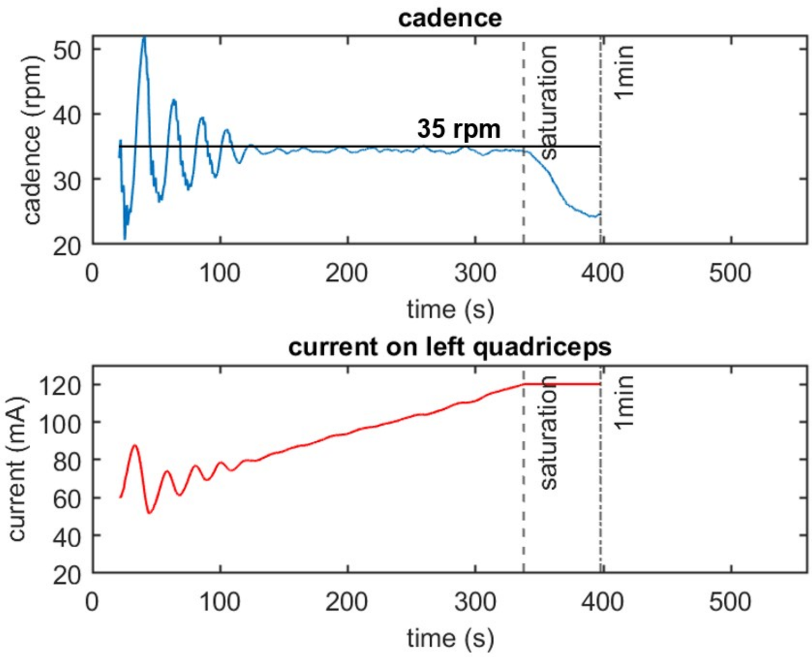

Figure 3.7: *Fourth trial of the test session number 7 in which stimulation at 40 Hz fixed has been tested. The filtered cadence is plotted in blue. A black solid line specify the target cadence (35 pm). The red plot shows the action of the PI controller on the current amplitude necessary to keep the cadence constant.*

reached. After reaching 120 mA the controller is not capable of compensate for fatigue anymore. After current saturation was reached, the cadence decreased with a trend visually similar to the response of a first order system. Observing the oscillation of the cadence in the initial phase after the beginning of the stimulation, it is possible to see that the amplitude of the oscillation increases from the first to the fourth trial as an effect of muscular fatigue. In particular in the fourth trial the muscles were almost exhausted and it took about 100s to the PI controller to stabilize the value of the cadence around 35 RPM. This was due also to the fact that the initial values of current amplitude were optimized for fresh muscles and was kept fixed for all the four trials.

3.3.3 Evaluation of the outcome measures

In Tab. 3.4 the values of distance covered in the time interval from the beginning of the stimulation until saturation is reached are reported. Each cell has a different colour to

Session	SDSS	DFTs	30Hz	40Hz	Mdn-IQR
1	303.9 m	393.0 m	313.1 m	284.1 m	**308.5-59.1**
2	101.5 m	444.0 m	313.0 m	346.3 m	**329.7-187.9**
3	31.5 m	557.3 m	438.0 m	486.4 m	**462.2-287.1**
4	175.4 m	253.9 m	419.9 m	422.4	**336.9-206.5**
5	311.9 m	456.5 m	437.6 m	534.6 m	**447.1-120.8**
6	19.9 m	321.6 m	684.3 m	633.2	**477.4-488.0**
7	564.1 m	999.7 m	804.5 m	615.8 m	**710.2-307.2**
8	150.0 m	513.1 m	338.5 m	428.1 m	**383.3-226.4**
9	14.7 m	212,1 m	296.9 m	326.7 m	**254.5-198.4**
10	569.2 m	391.7	948.9 m	500.5 m	**534.9-313.0**
11	8.6 m	597.4 m	1332.5 m	611.8 m	**605.1-668.7**
12	436.7 m	428.6 m	1310.8 m	N.A.	**873.8-661.6**
Mdn-IQR	**162.7-348.6**	**436.3-178.6**	**437.8-550.9**	**493.5-229.5**	

Legend
1st trial
2nd trial
3rd trial
4th trial

Table 3.4: *Distance covered in each trial from the beginning of the stimulation until saturation is reached.*

specify whether the trial had been executed as the first, second, third or fourth of the day. The median value and the interquartile range computed for the different testing sessions and for the different stimulation strategies are also reported.

Interestingly, the median value for the SDSS trials resulted to be less than a half of the median values obtained for DFTs, constant 30 Hz and constant 40 Hz. In contrast, the interquartile ranges are comparable for all the stimulation strategies.

The effect of muscle training can be deduced from the values of the median computed on each testing day, where an increasing trend is visible. Over the two months in which the acquisitions were made, the muscles of the subject enhanced their fatigue resistance. In order to not exceed the 15 minutes duration for each trial, it became necessary to increment the back gear to 6 in the 11^{th} acquisition and to 7 in the 12^{th}. Nevertheless, the 40 Hz trial of the last session (executed as first) was stopped after 15 minutes without reaching saturation.

To better visualize the impact of muscle training over time, the median and the

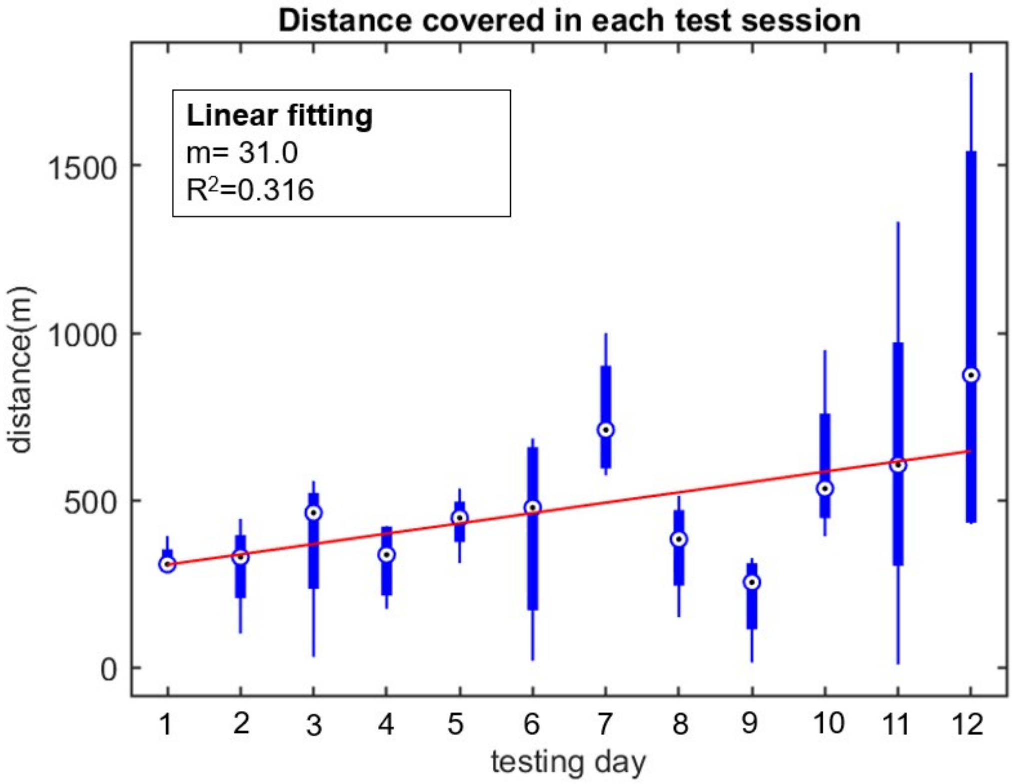

Figure 3.8: *Distance covered from the beginning of the stimulation, until saturation is reached. For each test session the median value together with the interquartile ranges are reported. The median value is represented by the white circle, while the thick blue lines represent the interquartile ranges. A linear fitting of the median value has been computed and it is represented in red.*

interquartile ranges of the distance covered before saturation have been plotted in Fig. 3.8. In the same figure, a linear fitting of the median values has been reported.

Session	SDSS	DFTs	30Hz	40Hz	Mdn-IQR
1	60.7 m	73.8 m	70.3 m	69.4 m	**70.1-6.8**
2	61.0 m	80.5 m	64.5 m	N.A.	**64.5-14.6**
3	110.1 m	90.0 m	87.2 m	81.8 m	**88.6-15.6**
4	83.0 m	75.4 m	79.4 m	83.6	**81.2-5.9**
5	80.0 m	90.7 m	100.0 m	N.A.	**90.7-15**
6	100.1 m	84.6 m	100.1 m	87.8	**94.0-13.9**
7	101.9 m	N.A.	101.7 m	95.8 m	**101.7-4.6**
8	N.A.	94.3 m	84.7 m	90.5 m	**90.5-7.2**
9	107.9 m	82.6 m	77.8 m	90.8 m	**86.7-19.2**
10	87.9 m	94.6 m	N.A.	89.8 m	**89.8-5.0**
11	112.3 m	95.8 m	113.7 m	98.8 m	**105.6-15.7**
12	94.9 m	102.6 m	113.0 m	N.A.	**102.6-13.6**
Mdn-IQR	**94.9-25.65**	**90.0-13.5**	**87.2-23.1**	**89.8-8.9**	

■	1st trial
■	2nd trial
■	3rd trial
■	4th trial

Table 3.5: *Distance covered in the minute after saturation is reached. Note that in some trials it was not possible to pedal one minute after saturation.*

In Tab. 3.5 the values of distance covered in the minute after saturation are listed for all the trials in which it was possible to pedal the entire minute. The medians and interquartile ranges are also computed on each day and over the different stimulation strategies. For every single strategy an increasing trend over time can be observed. In Fig. 3.9 to Fig. 3.12 it is possible to see the scatterplots of the values of distance covered in the last minute for the different stimulation strategies. The linear fitting has been computed for each strategy to highlight the increasing trend. The slope of the fitted line and the coefficient of determination for the linear fitting are reported for each strategy.

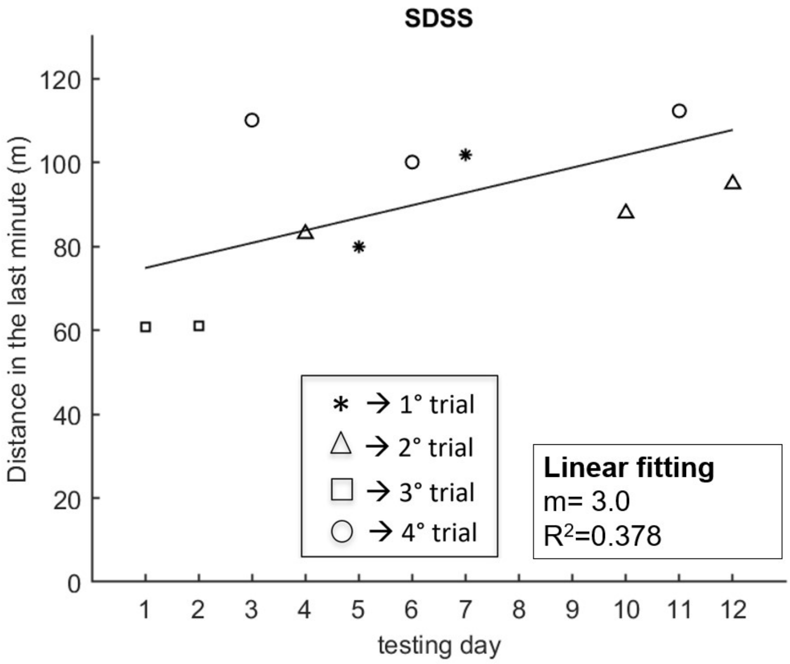

Figure 3.9: *Scatterplot of the distance covered in the minute after saturation for SDSS trials, together with the linear fitting over the 12 acquisitions*

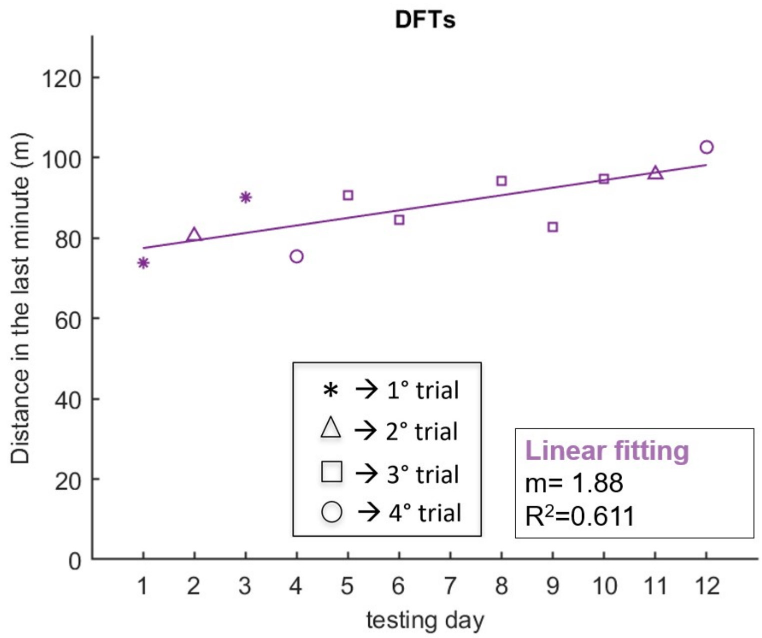

Figure 3.10: *Scatterplot of the distance covered in the minute after saturation for DFTs trials, together with the linear fitting over the 12 acquisitions*

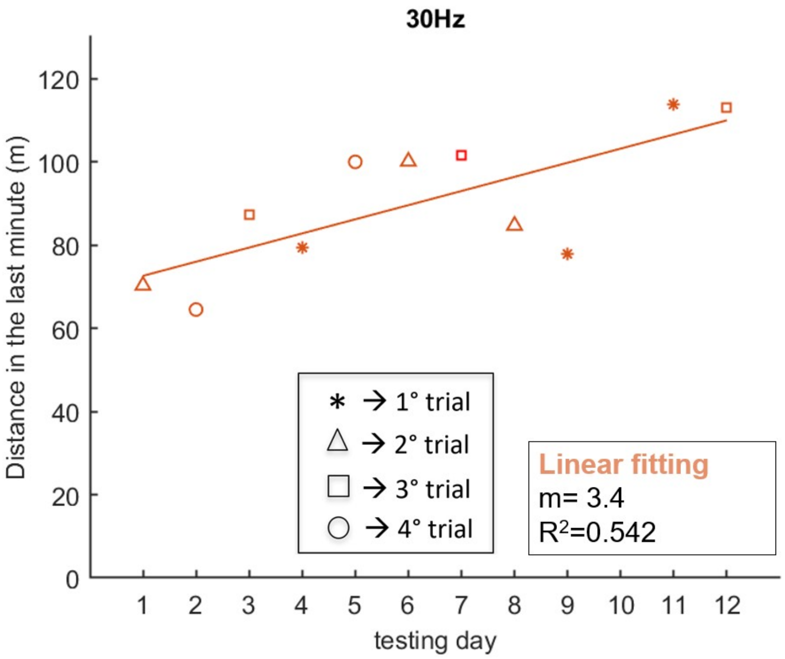

Figure 3.11: *Scatterplot of the distance covered in the minute after saturation for 30 Hz trials, together with the linear fitting over the 12 acquisitions*

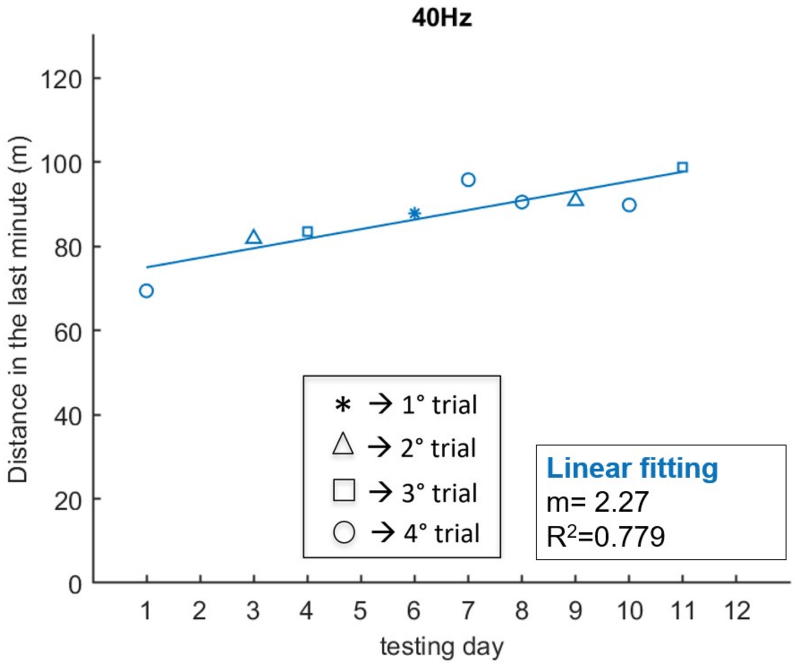

Figure 3.12: *Scatterplot of the distance covered in the minute after saturation for 40 Hz trials, together with the linear fitting over the 12 acquisitions*

3.3.4 Results of the statistical analysis

For what concerns the saturation time, in Fig. 3.13 the boxplot of T_{sat} (in seconds) with respect to the four different stimulation strategies is depicted. As highlighted in the plot, the values of T_{sat} of SDSS result to be statistically lower when compared to stimulation at constant frequency of 30 Hz (p-Value = 0.014) and to stimulation at constant frequency of 40 Hz (p-Value = 0.021). DFTs don't demonstrate a statistically relevant increase in the saturation time when compared to SDSS (p-Value = 0.0767), yet a net difference between the values of SDSS and DFTs is visually observable from the boxplot. The median values of saturation time for DFTs, 30 Hz fixed and 40 Hz fixed are above 200s whilst for SDSS the median value is below 100s. The stimulation strategy that shows the higher variability is 30 Hz fixed. Also for SDSS the variability is relevant. DFTs and constant 40 Hz are characterized by a much limited dispersion of the T_{sat} measurements over testing sessions.

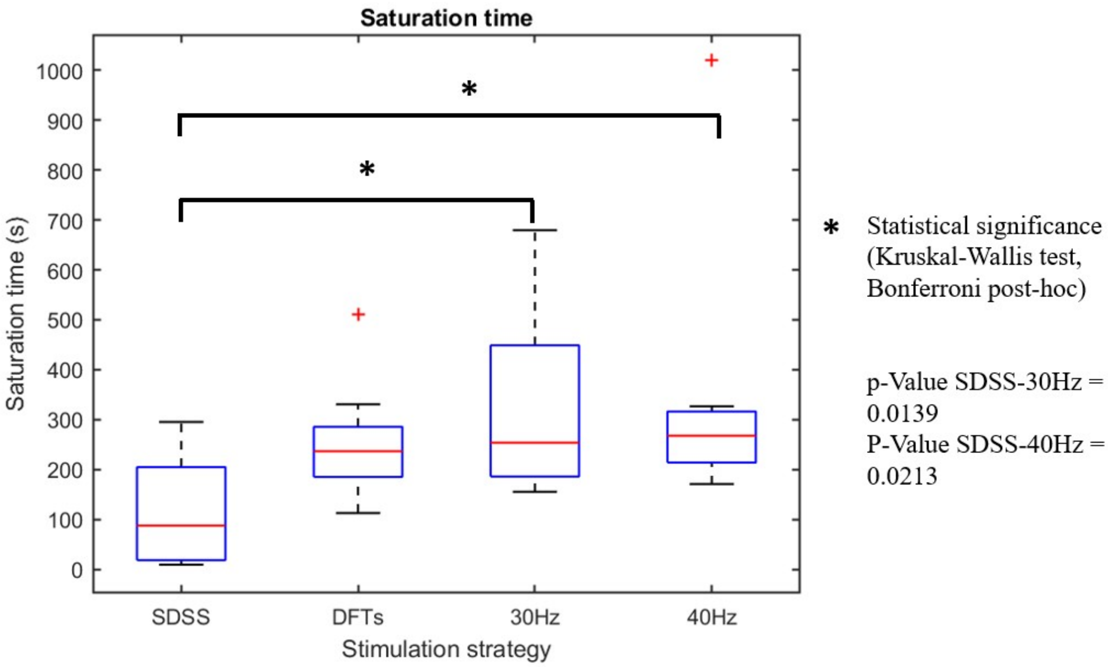

Figure 3.13: *Boxplot of the saturation time with respect to the stimulation strategy. The saturation time for SDSS results statistically lower when compared to the saturation times of constant frequency at 30 Hz and constant frequency at 40 Hz.*

In Fig. 3.14 the results of the statistical analysis of the root mean square error of the cadence with respect to the stimulation strategy are displayed. No statistically significance could be found. From the boxplot in Fig. 3.14 it is possible to see that the median value of RMSE for SDSS results to be higher compared to the other strategies. The values of RMSE for SDSS also show a markedly greater variability. The medians and interquartile ranges of the other stimulation strategies are similar to each other.

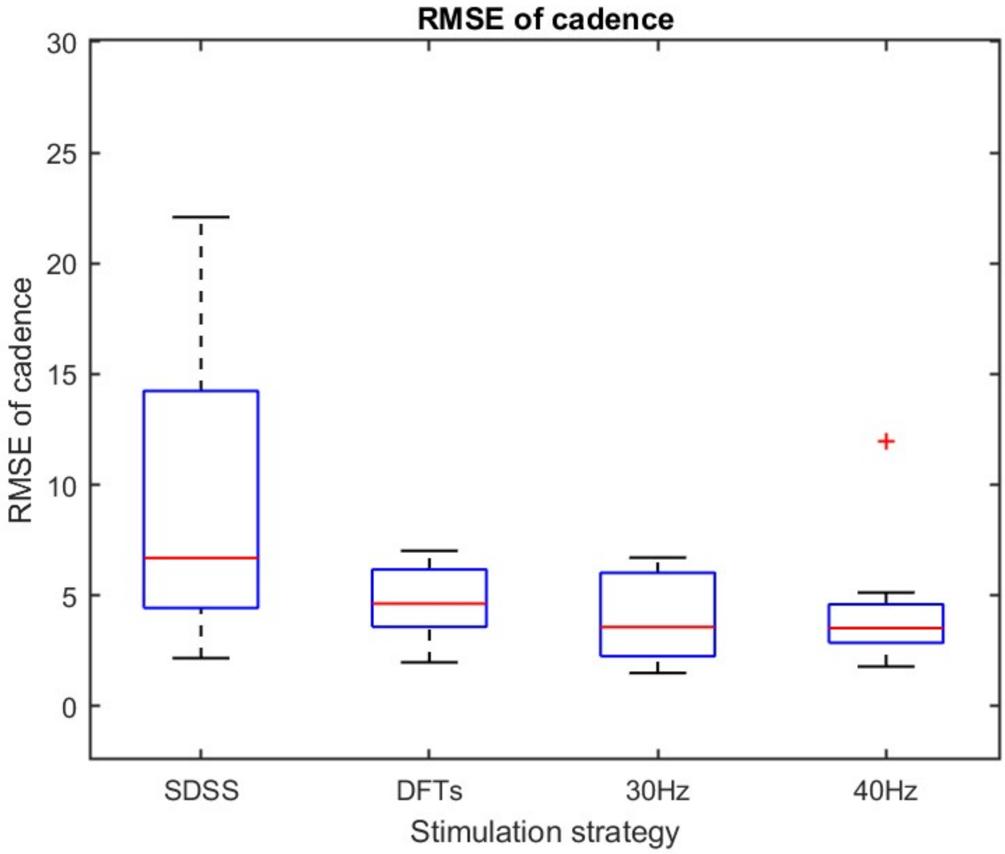

Figure 3.14: *Boxplot of the RMSE of the cadence with respect to the stimulation strategy.*

In Fig. 3.15 the boxplot of the distance covered in the minute after saturation is shown. No statistically significant difference can be highlighted between the four stimulation strategies. The median values seems comparable for all the strategies. What can be seen is that for SDSS and for stimulation at constant frequency of 30 Hz, the variability of the measurements is markedly higher than for DFTs and constant frequency stimulation at 40 Hz.

The boxplot reported in Fig. 3.16 represents once more the saturation time, analyzed with respect to the trial order. No significant difference can be highlighted. The

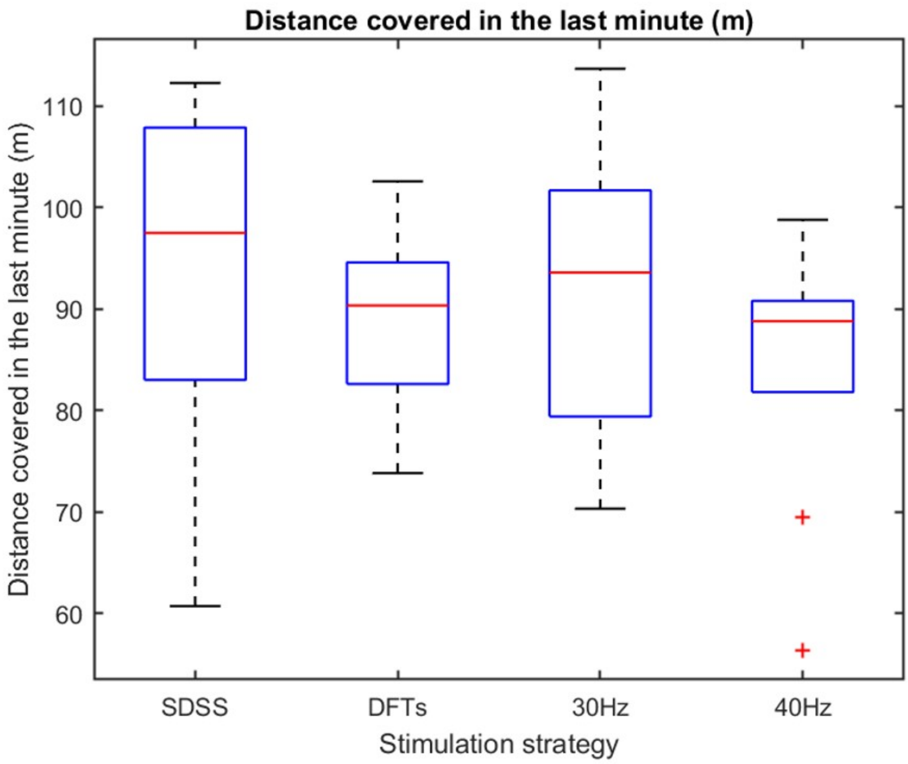

Figure 3.15: *Boxplot of the distance covered in the minute after saturation, with respect to the stimulation strategy.*

median value of the fourth trial is the lowest one and this can be explained by the effect of muscle fatigue. Moreover, the fourth trial presents the highest variability. The variability of the first trial is also relatively high.

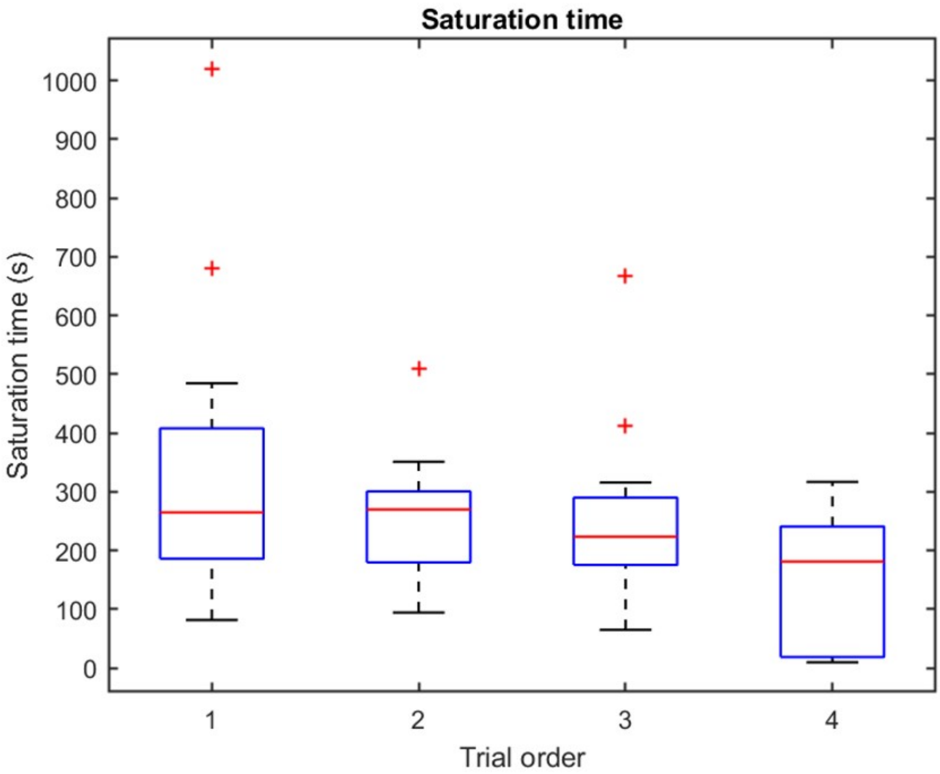

Figure 3.16: *Boxplot of the saturation time with respect to the trial order.*

In Fig. 3.17 the RMSE of the cadence has been analyzed with respect to the trial order. The statistical tests evidenced no significant difference. Visually observing the boxplot it is possible to notice that the fourth trial is characterized by the highest RMSE. As already highlighted in Fig. 3.7, the fourth trial of one testing session is characterized by a consistent amount of muscle fatigue. The PI controller, especially in the first minutes, is not able to maintain the cadence at the target value, thus wide oscillations in the values of the cadence are present, as can be seen in Fig. 3.7. The values of RMSE of the cadence for the first, second and third trials are visibly smaller.

In the final trial, executed after the 12 acquisitions of the case study, the pilot was able to reach the target distance of 1200 m of the FES-bike race in eight minutes. In Fig. 3.18 in the first plot the values of cadence and of current amplitude for the left quadriceps are reported, highlighting the effect of the PI controller, which was set to keep the cadence at 40 rpm. In Fig. 3.19 the measurements taken through the Wahoo APP are also reported.

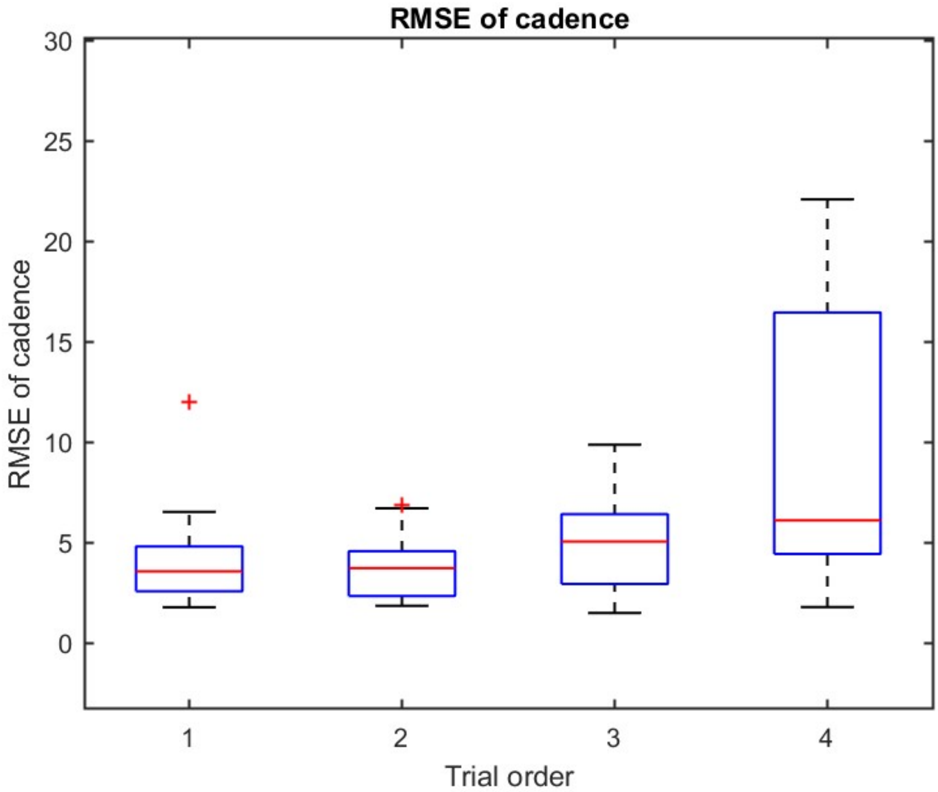

Figure 3.17: *Boxplot of the RMSE of the cadence with respect to the trial order.*

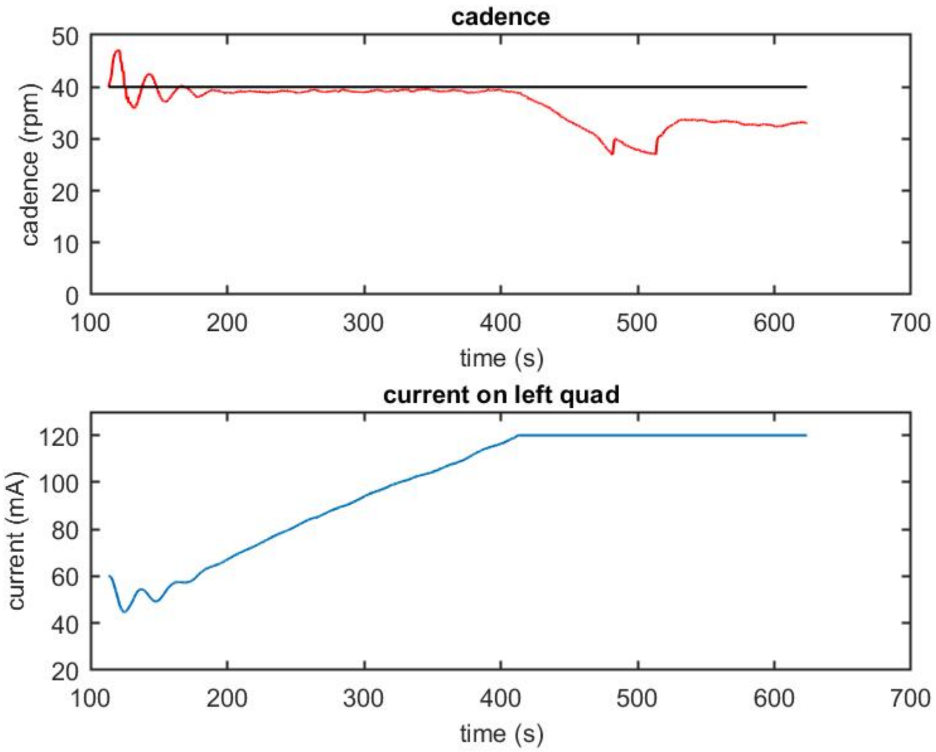

Figure 3.18: *Plots from the final trial executed at the end of the 12 acquisitions. In the first plot, the values of the cadence are depicted in red and a solid black line point out the target value of 40 RPM. In the second plot, the values of current amplitude for the left quadriceps are reported in blue*

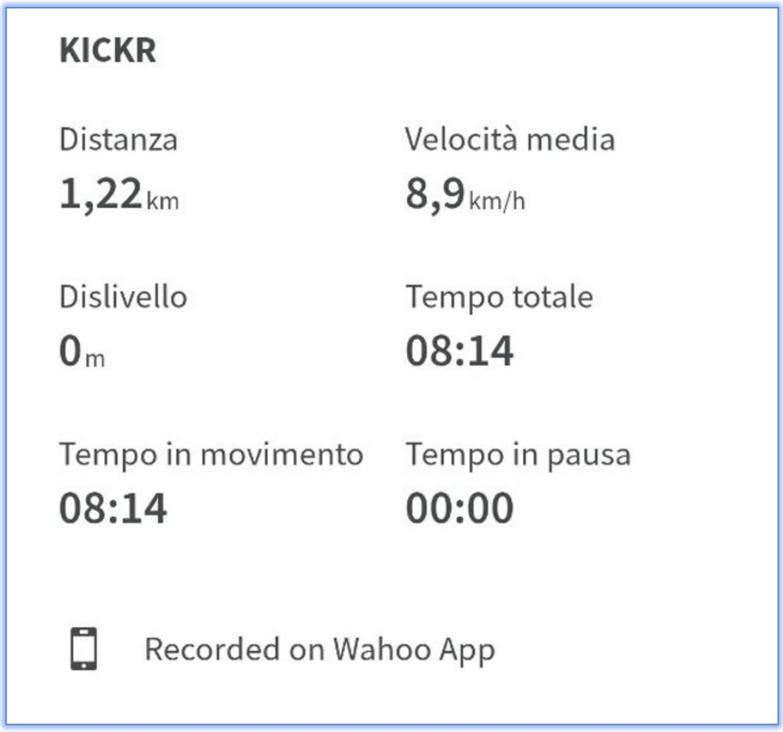

Figure 3.19: *Report of the measures taken through the Wahoo APP in the last trial. The pilot was able to cover 1200 m in 8 minutes.*

Chapter 4

Discussion

For what concerns the first objective of this work, i.e. the participation at CYBATHLON 2020 GLOBAL EDITION, it can be said that the performance obtained in the FES-bike race was not optimal, since the pilot was not able to cover the target distance of 1200 in the eight minute provided. Still, considering that the time available for training had been dramatically limited due to the Covid-19 pandemic, the covering of 850 m in 8 minutes is impressing, as it means an average linear distance of 6.4 Km/h. The competition was also an opportunity to work collaboratively with the pilot and to have many feedbacks about the system. Participanting in CYBATHLON 2020 required the POLIMIRehaMove team to face the challenges of FES-cycling and was therefore a chance to work on optimizing the stimulation parameters and the training strategy in an effort to maximize the performance on the trike.

For what concerns the case study, its aim was to investigate the influence of different stimulation strategies on the performance obtained during a FES-cycling task, in terms of muscle fatigue. The results of the 12 acquisitions evidenced a significant difference in the cycling performance when comparing SDSS with the other three stimulation strategies. Notably, the values of saturation time for SDSS resulted to be significantly smaller with respect to the stimulation at constant 30 Hz and constant 40 Hz. The values of T_{sat} for DFTs were visually higher compared to SDSS, but the difference didn't turn out to be statistically significant. Furthermore, the variablity of the saturation time for SDSS demonstrated to be truly high. In particular, in the testing sessions in which SDSS was executed as the fourth trial (i.e. when muscles were already considerably fatigued) the saturation was reached almost immediately, with trials lasting less then 40 seconds. The RMSE of the cadence was markedly higher for the SDSS, although no statistical significance was found. The quality of the muscle contraction induced by SDSS was visually worse as compared with the other stimulation strategies, it seemed not totally tetanic, thus the pedalling movement resulted to be less smooth.

These findings are in contrast with some recent studies on SDSS [39, 40, 8] that evidenced a positive effect of the distributed stimulation in reducing muscle fatigue. However, Two of these studies, namely the one conducted by Maleşević et al. [39] and the one conducted by Nguyen et al. [40] tested SDSS during isometric contractions. Thus, the conclusions drawn in these studies are difficult to be transferred to a dynamic task as cycling. Furthermore, in [40] SDSS was applied to the gastrocnemius muscle. The task analyzed by Laubacher et al. in [8] involved isokinetic contractions of the quadriceps and it was choosen by the Authors to simulate the knee joint movement of recumbent cycling. The dynamometer controlled the angular range of motion at the knee joint from 40 to 120 deg (with 180 deg indicating straight leg) at an angular velocity of 110 deg/s, which corresponds to a cycling cadence of 50 RPM. Although the dynamic knee extension task described in [8] could be compared to FES-induced cycling, the intensities of the stimulation used by Laubacher et al. were much lower than the ones required for overcoming rough surfaces and inclines in outdoor cycling. Furthermore, the studied mentioned so fare were carried out on non-trained subject.

In January 2021 Schmoll et al. [43] published a study in which they compared different electrode configurations for SDSS with the conventional two electrodes configuration. The task also involved isokinetic contractions of the quadriceps similar to the one described by Laubacher et al. [8]. Two of the four SDSS configurations which were tested were adapted from [8] and [39]. The results of the study didn't demonstrate a remarkable effect in fatigue reduction for any of the tested SDSS configuration. Differently from [8], in the study conducted by Schmoll et al. [43], the stimulation amplitudes used to carry out the tests were considerably high, comparable to the ones used in the present study. Thus the authors hypothesized that, the use of high stimulation amplitude in SDSS could cause a certain degree of spillover, leading to the recruitment of additional motor-units indented to be stimulated by a neighboring electrode. Therefore, they concluded that the effects of SDSS could be less pronounced at higher stimulation as a result of the loss of intra-muscular selectivity. The subjects that participated in [43] had been trained for at least four months before the tests.

The case study described in this work has several similarities with the study conducted by Schmoll et al., such as the high stimulation intensity used during the test sessions and the participation of one trained subject. Therefore, there is the possibility that the low performance of SDSS seen here could be related to the spill-over phenomenon hypothesized by Schmoll et al. On the other hand, Schmoll et al. didn't report a lower performance for SDSS, just a performance similar to the one obtained with conventional single electrode stimulation. Hence, some further factors may have affected the performance of SDSS in the present study. A highly relevant element to be taken into account is certainly the electrodes placement used for testing the SDSS strategy in the present study. In Fig. 2.13 it is possible to see that the electrodes chosen for SDSS testing are quite small and have been placed relatively distant to each other. This have probably caused the quadriceps to not reach a complete tetanic contraction, with a consequent reduction of induced power for the same stimulation intensity.

Probably to obtain a real advantage from SDSS, a precise and balanced electrodes configuration must be found. The electrodes must be sufficiently distant to recruit different motor fibers, reproducing the effect of the physiological asynchronous recruitment of the motor fibers, even when high values of currents cause some spillover. At the same time the electrodes must be close enough to enable the muscle to reach a tetanic contraction.

Another element that was highlighted by this Master thesis is the crucial importance of muscle training on FES-cycling performance. In particular, during the two months of data collection, the fatigue resistance of the subject muscles increased visibly as demonstrated by the augmented saturation time and the higher distance covered in the minute after saturation. To keep the saturation time within the fifteen minutes of the protocol, it became necessary to increase the back gear in the last two acquisitions.

Regular training over a long period of time is crucial in overcoming the rapid fatigue problem of FES applications, and in particular of FES-cycling. This has been proven by the fact that the pilot, after participating in the acquisitions for the case study twice a week for two months, was finally able to reach the distance 1200m of the CYBATHLON competition in eight minutes.

4.1 Conclusions and future developments

The case study presented here demonstrated a lower performance of SDSS compared to the other stimulation strategies tested (DFTs, fixed frequency of 30 Hz and fixed frequency of 40 Hz) during a protocol of FES-cycling. These findings are of interest since to date no previous study can be found that analyzes SDSS performance in a dynamic cycling movement. The main two limitations of the present study are the inclusion of a single subject in the case study, and the lack of an accurate measurement of the torque produced at the pedals, which could have given a more direct indication of the cycling performance and of the stimulation efficiency.

A main factor that influences the SDSS performance is the electrode placement. In the present study, the electrodes for SDSS testing have been placed distally and markedly distant to each other (Fig. 2.13). With the aim to further investigate the effect of electrodes placement in SDSS, other twelve acquisitions are going to be made using a different electrodes configuration for the SDSS strategy. Notably, the four small electrodes are going to be placed proximally on the quadriceps instead of distally and they are going to be closer to each other.

For the next twelve acquisitions a new testing protocol has also been defined in order to achieve a final conclusion about the best stimulation strategy and to further train our pilot. The new protocol has been structured to facilitate a comparison with the performance obtained in CYBATHLON 2020 global edition. Moreover it introduces a more flexible management of the gears, to be exploited according to the level of training reached.

The testing sessions are going to be twelve, with at least 24 hours of rest between consecutive sessions. The tested stimulation strategies are going to be the same analyzed in the present study (SDSS with a different electrode configuration, DFTs, stimulation at constant frequency of 30 Hz and at constant frequency of 40 Hz).
In every test session four trials are going to be executed, in a randomized order, with 6 minutes of rest between each trial. The same PI controller described in 2.5.2 is going to be used to keep the cadence of pedalling constant at 40 RPM. The saturation values for the current amplitude are going to be the same as described in Tab. 2.7.
To counteract the effect of fatigue, the values of current amplitude for all the muscle groups at the beginning of the second, third and fourth trials are going to be incremented with respect to the values used in the first trial. In particular, the increment will be of 5 mA for the second trial, of 10 mA for the third trial and of 15 mA for the fourth trial, as described in Tab. 4.1.

Muscle	**1st trial**	**2nd trial**	**3rd trial**	**4th trial**
Quadriceps	60 mA	65 mA	70 mA	75 mA
Gluteal muscles	60 mA	65 mA	70 mA	75 mA
Hamstrings	60 mA	120 65 mA	70 mA	75 mA
Gastrocnemius	55 mA	60 mA	65 mA	70 mA

Table 4.1: *Values of the initial current amplitudes for each trial in the new testing protocol.*

The stimulation is going to be stopped when the distance of 1200 m is reached or whether the cadence drops below 20 rpm. Each trials will last no more than 10 minutes. The stimulation will be interrupted at 10 minutes even if the target distance is not reached. During each trial the pilot can change the gears with the purpose to have a smooth pedalling and to reach the target distance in the shortest period of time. The starting back gear for the first trial of the new protocol is going to be gear 7 or 8 (17 or 15 teeth).

The performance is going to be evaluated in terms of:

- Whether the target distance of 1200 m is covered or not
- Time elapsed from the beginning of the stimulation until the target distance is covered
- The final value of current amplitude when the target distance is reached
- The charge delivered to the muscles to reach the target distance
- Saturation time
- Root mean square error of the cadence with respect to the target value of 40 RPM

Torque sensors at the pedals are going to be integrated in the trike and more subjects are going to be involved.

This thesis work was an opportunity to directly investigate the challenges of outdoor FES-cycling and to shed further light on the efficacy of some state-of-the-art stimulation techniques when applied in this field. What can be concluded from this study is the importance of carry out measures and tests directly during FES-cycling to have concrete results that could materially help the diffusion of FES-cycling exercises among the SCI population. This study has also demonstrated once more the importance of regular training as one of the key element to overcome the well-known problem of rapid muscle fatigue related to all FES applications.

List of figures

List of tables

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